

EPA Registration 70506-18

Vol.1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 25 2005

Rebecca A. Clemmer
United Phosphorus Inc
423 River View Plaza
Trenton, NJ 08611

Subject: Submission of Storage Stability and Corrosion Characteristics Study
Bifenthrin Technical Insecticide/Miticide
EPA Reg. No. 70506-18
Your Letter Dated: June 14, 2004

Dear Ms. Clemmer:

The data submitted corresponding to guideline reference 830.6317 (Storage stability) and 830.6320 (Corrosion Characteristics) are acceptable. The review has been inserted in the file for the subject product.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,

A handwritten signature in black ink, appearing to read "G. LaRocca".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

DATE OUT: 17/MAR/2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP []
DP BARCODE No.: D312238 REG. No.: 70506-18
PRODUCT NAME: Bifenthrin Technical Insecticide/Miticide
COMPANY: United Phosphorous Incorporation
PCC: 128825; Decision No.: 352095

FROM: Shyam B. Mathur,
Team Leader Product Chemistry
Technical Review Branch/RD (7505C)

SB Mathur
03/17/05
me

TO: BeWanda Alexander/George Larocca, RM 13
Insecticide Branch/RD(7505C)

INTRODUCTION

The registrant has submitted the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies for bifenthrin technical. The study results have been submitted under MRID No. 464142-01. The TRB has been asked to review the product chemistry data submitted.

SUMMARY OF FINDINGS

1. The subject product is Technical Bifenthrin containing bifenthrin as the active ingredient with product label claim of 99.4%.
2. The studies were performed at JAI Research Foundation, Valvada in India. The studies were conducted in accordance to Good Laboratory Practice Principles as published by OECD in 1998, No.1, [ENV/MC/CHEM(98)17].
3. The samples were stored in six commercial containers (Fibre board drum with double HDPE liner) at room temperature under warehouse conditions. One container was opened initially and one container was opened at each sampling intervals i.e., after 3, 6, 9 and 12 months of storage. The remaining containers were drawn after 18 months for final evaluations.

DP BARCODE No.: D312238 REG. No.: 70506-18 PRODUCT NAME: Bifenthrin
Technical Insecticide/Miticide

4. The test substance was evaluated with respect to the following tests:

Corrosion characteristics: Perforation, darkening, leaking or rust at the seam, appearance of the container (by visual- shape, crack, color)

Storage stability: Appearance, acidity, and AI content. The AI content was determined by HPLC/UV(254 nm).

5. There was no degradation or loss of bifenthrin was observed after 12 months of storage. Before storage (0 day), the AI content was 99.04% w/w. After storage at room temperature for a period of 3, 6, 9 and 12 months, the AI content was 98.99, 98.80, 98.75 and 98.64% w/w respectively.

6. There were no signs of corrosion characteristics. There were no perforation, leaking, rust, darkening, change in the shape or cracks observed on the container of the bifenthrin technical at zero day as well as after 3, 6, 9 and 12 months.

CONCLUSIONS

The TRB has reviewed the product chemistry data submitted for the Bifenthrin technical and has concluded that:

The data submitted for the guideline 830.6317(one year storage stability) and 830.6320 (corrosion characteristics) satisfy the data requirements of 40CFR§158.190 and are acceptable.

DP BARCODE No.: D312238 REG. No.: 70506-18 PRODUCT NAME: Bifenthrin
Technical Insecticide/Miticide

HPLC parameters and Instrument

Instrument: HPLC (Shimadzu, LC-10 AT Pump, SPD-10A UV-VIS detector with CLASS 10A software).

Detector: operating at 254 nm

Column: ODS, 5 μ m, 25 mm x 4.6 mm id

Guard column: Alltech, Allguard, C18, 5 μ m, 7.5 x 4.6 mm id

Mobile phase: Acetonitrile (80) : water (20)

Flow rate: 2.0 ml/min

Samples injected: 0.5 mg/ml oryzalin and 0.05% (v/v) dimethylphthalate (IS) in acetonitrile:water (1:1, v.v).

Volume injected: 20 μ L

484142-00



United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

June 9, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submission of Study
Bifenthrin Technical (EPA Reg. No. 70506-18)

Dear Mr. LaRocca:

Enclosed please find a storage stability and corrosion characteristics study, submitted in support of the registration of UPI Bifenthrin Technical:

48414201 Storage Stability and Corrosion Characteristics of Bifenthrin Technical
(Interim Report - 12 Months). United Phosphorus, Inc., Study 4210,
May 29, 2004. 113 p.

Enclosed you will find three copies of the study. This letter will serve as the transmittal document.

Please contact me if you have any questions.

Very truly yours,

A handwritten signature in cursive script that reads 'Rebecca A. Clemmer'.

Rebecca A. Clemmer
rclemmer@upi-usa.com

File: RAC-2004-040
Bifenthrin Technical Registration File

CC: A. Tillman
J. Pritchard

**United Phosphorus, Inc.**

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
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Rebecca A. Clemmer
rclemmer@upi-usa.com

File: RAC-2004-040
Bifenthrin Technical Registration File

CC: A. Tillman
J. Pritchard



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 1, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

UNITED PHOSPHORUS INC
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-DEC-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Office of Pesticide Programs
Registration Division (7505C)

INSECTICIDE BRANCH

F a x

Name: Rebecca Clemmer
Organization: UPI
Fax Number: 609-392-0808
Phone Number: 609-392-8200

From: George T. LaRocca,
Product Manager (13)
Phone Number: 703/305-6100
Fax Number: 703/605-1225

Date: August 2, 2004

Subject: Bifenthrin Technical/70506-18

Cover plus 3 Pages:

Comments: See attached letter regarding data submittal deficiency. You can fax the omitted page to my attention at 703-605-1225.

2004
AUG 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

UNITED PHOSPHORUS INC
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

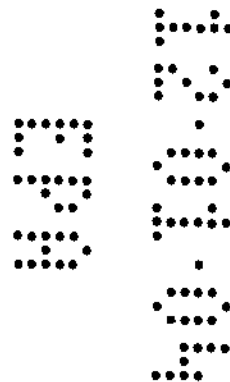
Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JUN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* Judging from the pagination of the study, page 81 was omitted from the submitted copy.





United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

June 9, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protections Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submission of Study
Bifenthrin Technical (EPA Reg. No. 70506-18)

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Enclosed please find a storage stability and corrosion characteristics study, submitted in support of the registration of UPI Bifenthrin Technical:

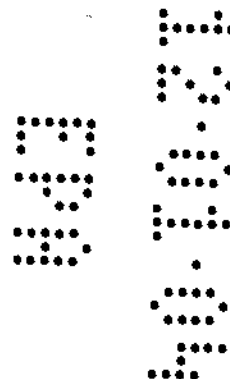
Reject (01) Storage Stability and Corrosion Characteristics of Bifenthrin Technical
(Interim Report - 12 Months). United Phosphorus, Inc., Study 4210,
May 29, 2004. 113 p.

Enclosed you will find three copies of the study. This letter will serve as the transmittal document.

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clemmer
rclemmer@upi-usa.com



CC: A. Tillman
J. Pritchard

Receipt for Section 3

S: 16-2073

Regulatory Type: ☐ Yes ☒ No

Application Type: ☒ Yes ☐ No

Company:

Risk Manager:

Product #: Product Name:

Chemical #:

Mo Top: Me Top:

Application Date: OPP Recvd Date:

Print End Date: Risk Manager Send Date:

Fast Track: ☐ Have been paid: ☐

Receipt Description:

Form 2: ☐ Signature Date: Form 3: ☐ Signature Date:

Receipt Content

Print Label

Enter More Information

15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 16, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

UNITED PHOSPHORUS INC
423 RIVERVIEW PARKWAY
TRENTON, NJ 08611

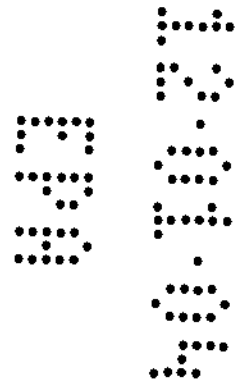
Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JUN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* Judging from the pagination of the study, page 81 was omitted from the submitted copy.





United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

June 9, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submission of Study
Bifenthrin Technical (EPA Reg. No. 70506-18)

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Enclosed please find a storage stability and corrosion characteristics study, submitted in support of the registration of UPI Bifenthrin Technical:

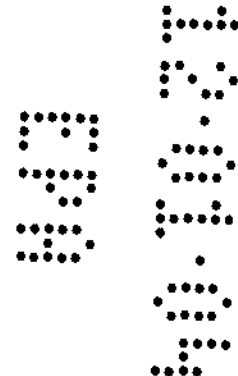
Reject (01) Storage Stability and Corrosion Characteristics of Bifenthrin Technical
(Interim Report - 12 Months). United Phosphorus, Inc., Study 4210,
May 29, 2004. 113 p.

Enclosed you will find three copies of the study. This letter will serve as the transmittal document.

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clemmer
rclemmer@upi-usa.com



File: RAC-2004-040
Bifenthrin Technical Registration File

CC: A. Tillman
J. Pritchard

2004-040



423 Riverview Plaza
Trenton, NJ 08611

Phone: (609) 392-8200, extension 18
Fax: (609) 392-0808

FAX

DATE: November 5, 2004
TO: Mr. George LaRocca
FROM: Rebecca A. Clemmer, Regulatory Affairs Manager
SUBJECT: Replacement of missing study page

MESSAGE:

Dear Mr. LaRocca:

Attached please find page 81 of the study
Storage Stability and corrosion Characteristics of Bifenthrin Technical (12 Months), Jai
Research Foundation Study 4210, May 29, 2004

which you indicated was missing from the Agency's copy.

Please contact me if you have any questions.

Rebecca A. Clemmer



United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

June 9, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submission of Study
Bifenthrin Technical (EPA Reg. No. 70506-18)

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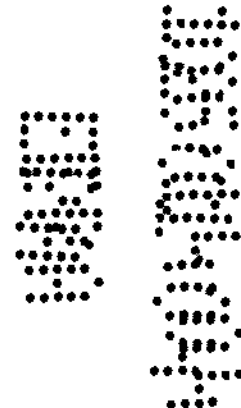
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Please contact me if you have any questions.

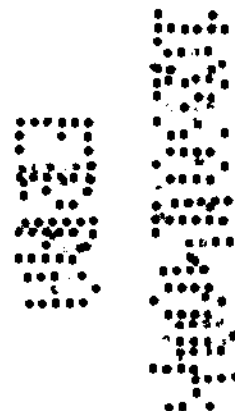
Very truly yours,

Rebecca A. Clemmer
rclemmer@upi-usa.com



File: RAC-2004-040
Bifenthrin Technical Registration File

CC: A. Tillman
J. Pritchard





United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 (phone)
(609) 392-0808 (fax)

Ann M. Tillman
Technical Director

June 28, 2004

Mr. George LaRocca, PM 13
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

This letter is to request Gold Seal Letters (3 copies each) for the following products:

PRODUCT	EPA REG. NO.
Tengard MUP Insecticide	70506-5
Tengard SFR One-Shot Insecticide	70506-6
Tengard HG Insecticide	70506-7
Perm-Up 3.2 EC Insecticide	70506-9
Cypermethrin Technical Insecticide	70506-10
Bifenthrin Technical Insecticide	70506-18
Cypermethrin 2.0 EC Insecticide	70506-19
Up-Cyde 2.5 EC Insecticide	70506-20
Cypermethrin 2.5 EC	70506-21
Bifenthrin SC Lawn & Greenhouse Insecticide	70506-22
UP-Star SC Lawn and Nursery Insecticide	70506-23
UP-Star Gold Insecticide	70506-24

Please send them to my attention at the above address.

Sincerely,

Rebecca A. Clemmer
Regulatory Manager
Phone: 609-392-8200 x 18
e-mail rclemmer@upi-usa.com



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

November 1, 2004

I, **George Larocca**, Insecticide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.


Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

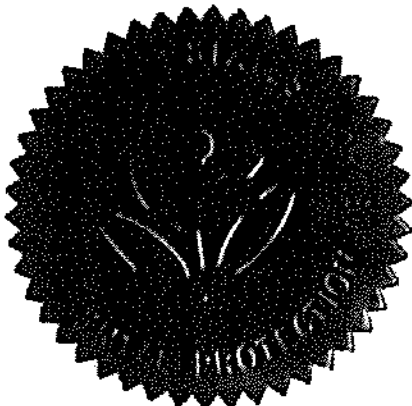
EPA has issued registration numbers for the product(s) listed below to:

**United Phosphorus Inc
423 Riverview Plaza
Trenton, NJ 08611**

**EPA Registration Number:
Name of Product:**

**70506-18
Bifenthrin Technical Insecticide/Miticide**


**George T. Larocca
Product Manager (03; 13)
Insecticide Branch
Registration Division (7505C)**



BIFENTHRIN Technical

Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin: [2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)

-2,2-dimethylcyclopropanecarboxylate*99.4%

OTHER INGREDIENTS 0.6%

TOTAL100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

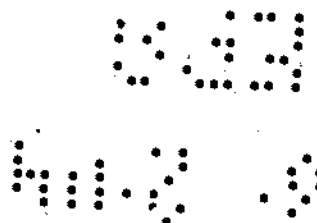
**FOR EMERGENCY MEDICAL ASSISTANCE, CALL
THE NATIONAL PESTICIDE INFORMATION CENTER 1-800-858-7378**

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611
NET CONTENTS :

EPA Reg. No. 70506-18
EPA Est. No. 41876 - IY- 1

NOT REVIEWED
In accordance with PR Notice 82-2
based on draft labeling dated ✓

7/24/04



PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning : May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This material requires further mixing before use

Only for formulation into an insecticide/miticide for

(1) The following uses:

Terrestrial Food/Feed Crops: Sweet Corn, Succulent Peas and Beans, Head and Stem Brassica Vegetables, Globe Artichoke, Cucurbits, Herbs, Bananas (import only), Legume Vegetables, Cotton, Field Corn (Grain and Silage), Popcorn, Field Corn Grown for Seed, Hops, Rapeseed, Canola, Crambe, Strawberries, Canberries, Lettuce (head), Pears, Citrus, Tomato, Peppers (bell and non-bell), Eggplant, Spinach, Tree Nuts, Grapes

Terrestrial Non-Food:

Termite and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Ornamental plants, trees, shrubs, and vines (woody)

Residential Lawns

Indoor Insect Control

Greenhouse Grown Ornamental Trees, Shrubs, Plants, Flowers

Non-bearing Fruit and Nut Trees

Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where foods may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (canning, bottling, wrapping, boxing), preparing, edible wastes, storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered a food area.

(2) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

**FOR CHEMICAL EMERGENCY : Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300**

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

EPA Approved. 1/12/2004

**UPI****United Phosphorus, Inc.**

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 (phone)
(609) 392-0808 (fax)

Ann M. Tillman
Technical Director

June 28, 2004

Mr. George LaRocca, PM 13
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. LaRocca:

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Bifenthrin Technical Insecticide	70506-18
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Up-Cyde 2.5 EC Insecticide	70506-20
Cypermethrin 2.5 EC	70506-21
Bifenthrin SC Lawn & Greenhouse Insecticide	70506-22
UP-Star SC Lawn and Nursery Insecticide	70506-23
UP-Star Gold Insecticide	70506-24

Please send them to my attention at the above address.

Sincerely,

Rebecca A. Clemmer
Regulatory Manager
Phone: 609-392-8200 x 18
e-mail rclemmer@upi-usa.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 30, 2004

I, George Larocca, Insecticide Branch, Registration Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.


EPA has issued registration numbers for the product(s) listed below to:

United Phosphorus Inc
423 Riverview Plaza
Trenton, NJ 08611

EPA Registration Number:
Name of Product:

70506-18
Bifenthrin Technical Insecticide/Miticide




George T. Larocca
Product Manager (03; 13)
Insecticide Branch
Registration Division (7505C)

FP2



United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

July 27, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk (Final Printed Labeling)
Office of Pesticide Programs (7504C)
U.S. Environmental Protections Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Final Printed Label
Bifenthrin Technical Insecticide/Miticide (EPA Reg. No. 70506-18)

Dear Mr. LaRocca:

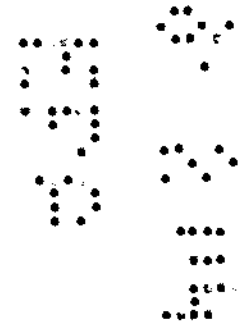
Enclosed for your files please find 5 copies of final printed labeling for the subject product. It incorporates changes approved by the Agency in January 2004. Because of the size and shape of the actual label, it has been cut to fit onto 8 1/2 x 11" paper.

Please contact me if you have any questions.

Very truly yours,

A handwritten signature in cursive script that reads 'Rebecca A. Clemmer'.

Rebecca A. Clemmer
rclemmer@upi-usa.com





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number
274811

Application for Pesticide - Section I

1. Company/Product Number 70506-18	2. EPA Product Manager G. LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) United Phosphorus, Inc/Bifenthrin Technical	PM # 13	
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below	<input checked="" type="checkbox"/> Final printed labels
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Submission of final printed labels.

Section III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Rebecca A. Clemmer		Title Regulatory Affairs Manager		Telephone No. (Include Area Code) 609-392-8200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Rebecca A. Clemmer</i>		3. Title Regulatory Affairs Manager			
4. Typed Name Rebecca A. Clemmer		5. Date July 27, 2004			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN 12 2004

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Amendment Adding Food/Feed Uses to Label
Bifenthrin Technical Insecticide/Miticide
EPA Reg. No.: 70506-18
Your Resubmission, Sent by Email on January 9, 2004

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,

A handwritten signature in cursive script that reads "Susan L. Stanton, for".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

Bifenthrin Technical Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)

-2,2-dimethylcyclopropanecarboxylate* 99.4%

OTHER INGREDIENTS 0.6%

TOTAL 100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

KEEP OUT OF REACH OF CHILDREN WARNING

United Phosphorus inc.
423 Riverview Plaza
Trenton, NJ 08611

EPA Reg. No. 70506-18
EPA Est. No.

ACCEPTED
JAN 12 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 70506-18

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL THE NATIONAL PESTICIDE
INFORMATION CENTER 1-800-858-7378**

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning

May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has

been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This material requires further mixing before use

Only for formulation into an insecticide/miticide for

(1) The following uses:

Terrestrial Food/Feed Crops: Sweet Corn, Succulent Peas and Beans, Head and Stem Brassica Vegetables, Globe Artichoke, Cucurbits, Herbs, Bananas (Import only), Legume Vegetables, Cotton, Field Corn (Grain and Silage), Popcorn, Field Corn Grown for Seed, Hops, Rapeseed, Canola, Crambe, Strawberries, Caneberries, Lettuce (head), Pears, Citrus, Tomato, Peppers (bell and non-bell), Eggplant, Spinach, Tree Nuts, Grapes

Terrestrial Non-Food:

Termiticide and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Ornamental plants, trees, shrubs, and vines (woody)

Residential Lawns

Indoor Insect Control

Greenhouse Grown Ornamental Trees, Shrubs, Plants, Flowers

Non-bearing Fruit and Nut Trees

Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where foods may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (canning, bottling, wrapping, boxing), preparing, edible wastes, storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered a food area.

(2) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

EPA Approved. 08/25/2003

Revision (notification): 09/05/2003

Draft Amendment: 10/02/2003, revised 01/09/2004



Elizabeth Brown
<brown@chemreg.com>
>

To: Susan Stanlon/DC/USEPA/US@EPA
cc: "Tillman Ann (E-mail)" <atillman@upi-usa.com>
Subject: UPI Bifenthrin EPA Reg No 70506-18

01/09/2004 12:37 PM

Susan:

In response to your phone call of January 7, 2004, and on behalf of our client United Phosphorus Inc., attached please find the following revised items for the amendment to UPI's bifenthrin technical label (amendment originally submitted on 10/6/03):

draft labeling
draft labeling with additional revisions marked as redline
data matrix - Agency Use
data matrix - Public File Copy

The certification with respect to citation of data previously filed for this amendment covers any changes in the data matrix; a new certification will not be filed unless you let me know otherwise.

Thanks very much. Please let me know if there is anything else that is needed. Would you please acknowledge safe receipt of this email and attachments by reply to this message?

Regards,
Elizabeth Anne Brown

<<20040109.Bifenthrin Technical label Amendment Food Uses.doc>> <<20040109.Bifenthrin Technical label Amendment Food Uses.Redline.doc>> <<20040109.data matrix.bifenthrin technical food crops - Agency.doc>> <<20040109.data matrix.bifenthrin technical food crops - Public.doc>>


Elizabeth Anne Brown, Ph.D.
Director, Scientific & Regulatory Affairs
ChemReg International
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192

Phone: 703-492-7905
Fax: 703-492-0668
Email: brown@chemreg.com

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20040109.Bifenthrin Technical label Amendment Food Uses.Red



20040109.data matrix.bifenthrin technical food crops - Agen



20040109.data matrix.bifenthrin technical food crops - Pub



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 1 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1 (830.1550)	Chemical identity	45654401	United Phosphorus Inc (UPI)	Own	
61-2a (830.1620)	Starting materials and manufacturing process	45654401	UPI	Own	
61-2b (830.1670)	Formation of impurities	45654401	UPI	Own	
62-1 (830.1700)	Preliminary analysis	45654401	UPI	Own	
62-2 (830.1750)	Certification of limits	45654401	UPI	Own	
62-3 (830.1800)	Analytical method	45654401	UPI	Own	
63-2 (830.6302)	Color	45654402	UPI	Own	
63-3 (830.6303)	Physical state	45654402	UPI	Own	
63-4 (830.6304)	Odor	45654402	UPI	Own	
None (830.7050)	UV/Visible Absorption	CITE ALL	FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
63-5 (830.7220)	Melting point	45838001	UPI	own	
63-7 (830.7300)	Density	45838001, 46008501, 46008502	UPI	own	
63-8 (830.7840)	Solubility	CITE ALL	FMC, Scotts, Andersons	pay	
63-9 (830.7950)	Vapor pressure	CITE ALL	FMC, Scotts, Andersons	Pay	
63-10 (830.7370)	Dissociation constant	CITE ALL	FMC, Scotts, Andersons	Pay	
63-11 (830.7550)	Octanol/water partition	CITE ALL	FMC, Scotts, Andersons	Pay	
63-12 (830.7000)	pH	45838001	UPI	own	
63-13 (830.6313)	Stability	45654403	UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
--	--	-------------------



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DATA MATRIX

Date: September 17, 2003

EPA Reg No./ File Symbol
70506-18

Page 2 of 4

Applicant's/Registrant's Name and Address:

United Phosphorus, Inc.
423 Riverview Plaza
Trenton, NJ 08611

Product: Bifenthrin Technical Insecticide/Miticide

Ingredient: Bifenthrin (PC 128825)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/reduction	45838001	UPI	Own	
830.6315	Flammability	45838001	UPI	Own	
830.6316	explosibility	45838001	UPI	Own	
830.7220	Boiling point	45838001	UPI	Own	
830.7370	Dissociation constant	45838001	UPI	own	
71-1b (850.2100)	Avian acute oral toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-2 (850.2200)	Avian dietary toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-4 (850.2300)	Avian reproduction	CITE ALL	FMC, Scotts, Andersons	Pay	
72-1 (850.1075)	Fish acute toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-2 (850.1010)	Invertebrate toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-3 (850.1025 - 1055)	Estuarine/marine toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1300)	Invertebrate Chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1350)	Invertebrate chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-5 (850.1400)	Fish life early life cycle	CITE ALL	FMC, Scotts, Andersons	Pay	
141-1 (850.3020)	Honeybee acute contact toxicity	CITE ALL	FMC, Scotts, Andersons	pay	
81-1 (870.1100)	Acute oral - rat	45654404	UPI	Own	
81-2 (870.1200)	Acute dermal - rabbit/rat	45645505	UPI	Own	
81-3 (870.1300)	Acute inhalation - rat	00155286	FMC	Old	
81-4 (870.2400)	Primary eye irritation - rabbit	00132522	FMC	Old	
81-5 (870.2500)	Primary dermal irritation - rabbit	00132521	FMC	Old	
81-6 (870.2600)	Dermal sensitization	00132523	FMC	Old	
81-8 (870.6200)	Acute neurotoxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
82-1 (870.3100)	90-Day feeding	CITE ALL	FMC, Scotts, Andersons	pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

9/17/2003



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 3 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-2 (870.3200)	21-Day dermal toxicity -- rats	CITE ALL	FMC, Scotts, Andersons	Pay	
82-7 (none)	Subchronic neurotoxicity - rat	CITE ALL	FMC, Scotts, Andersons	pay	
83-1a (870.4100)	Chronic feeding toxicity -- rodent	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-1b (870.4100)	Chronic feeding toxicity -- dog	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2a (870.4200)	Oncogenicity -- rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2b (870.4200)	Oncogenicity -- mouse	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3a (870.3700)	Teratogenicity -- rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3b (870.3700)	Teratogenicity -- rabbit	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-4	2-Generation Reproduction Study	CITE-ALL	FMC	Pay	
OPPTS 870.6300	Developmental Neurotoxicity	Data gap			
84-2	Mutagenicity studies	CITE-ALL	FMC, Scotts, Andersons	Pay	
84-4	Other genotoxic effects	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-1 (870.7485)	General metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-2	Dermal absorption	CITE-ALL	FMC, Scotts, Andersons	Pay	
161-1	Hydrolysis	CITE ALL	FMC, Scotts, Andersons	Pay	
161-2	Photodegradation in water	CITE ALL	FMC, Scotts, Andersons	Pay	
161-3	Soil photolysis	CITE-ALL	FMC	Pay	
162-1	Aerobic soil metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
163-1	Adsorption/desorption	CITE ALL	MC, Scotts, Andersons	Pay	
163-2	Lab volatility	CITE ALL	FMC	Pay	
164-1 (875.2200)	Field soil dissipation	CITE-ALL	FMC, Scotts, Andersons	Pay	
165-4	Bioaccumulation in fish	CITE-ALL	FMC, Scotts, Andersons	pay	
Special studies	Other	CITE ALL	Pyrethroid Working Group	pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 4 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
132-1 (857.2100)	Foliar residue dissipation	CITE ALL	FMC, Scotts, Andersons	Pay	
133-3 (875.2400, 2500)	Dermal exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
133-4 (857.2500)	Inhalation exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
201-1, 202-1 (840.1100, 835.4200)	Spray drift and droplet size	CITE ALL	UPI is a member of the Spray Drift Task Force	Own	
171-4a	Nature of residue - plants	CITE ALL	FMC	Pay	
171-4b	Nature of residue - livestock	CITE ALL	FMC	Pay	
171-4c	Residue analytical method - plants	CITE ALL	FMC	Pay	
171-4d	Residue analytical method - animals	CITE ALL	FMC	Pay	
171-4e	Residue storage stability	CITE ALL	FMC	Pay	
171-4j	Magnitude of residues - meat/milk/poultry/egg	CITE ALL	FMC	Pay	
171-4k	Magnitude of residues - field crop trials	CITE ALL	FMC, IR-4	Pay	
171-4l	Magnitude of residues - processed commodities	CITE ALL	FMC	Pay	
171-4m	Multi-residue method	CITE ALL	FMC	Pay	
165-1	Confined rotational crop	CITE ALL	FMC	Pay	
165-2	Field rotational crop	CITE ALL	FMC	Pay	

40

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: January 9, 2004	EPA Reg No./ File Symbol 70506-18	Page 1 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			United Phosphorus Inc (UPI)	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
			UPI	own	
			UPI	own	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			UPI	own	
			UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 1/4/2004
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: January 9, 2004	EPA Reg No./ File Symbol 70506-18	Page 2 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
42			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	own	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			UPI	Own	
			UPI	Own	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 1/4/2004
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DATA MATRIX

Date: January 9, 2004

EPA Reg No./ File Symbol

70506-18

Page 3 of 4

Applicant's/Registrant's Name and Address:

United Phosphorus, Inc.

423 Riverview Plaza

Trenton, NJ 08611

Product: Bifenthrin Technical Insecticide/Miticide

Ingredient: Bifenthrin (PC 128825)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
43			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC	Pay	
			FMC, Scotts, Andersons	Pay	
			MC, Scotts, Andersons	Pay	
			FMC	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			Pyrethroid Working Group	pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

1/4/2004



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date: January 9, 2004	EPA Reg No./ File Symbol 70506-18	Page 4 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC, Scotts, Andersons	Pay	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Spray Drift Task Force	Own	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC, IR-4	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

1/4/2004

Needs minor revisions

Bifenthrin Technical Insecticide/Miticide

FOR FORMULATION USE ONLY

*Discussed w/ E. Brown
1/7/04. She will revise
matrix and label
and resubmit.
Closed out w/
code 13 on 1/7/04
S. L. Shute*

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)
-2,2-dimethylcyclopropanecarboxylate*.....

99.4%✓

OTHER INGREDIENTS

0.6%✓

TOTAL

100.0%✓

*Cis Isomers 97% minimum, trans Isomers 3% maximum.✓

KEEP OUT OF REACH OF CHILDREN WARNING

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611

EPA Reg. No. 70506-18
EPA Est. No. ✓

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.✓

If swallowed	<ul style="list-style-type: none">Call a poison control center or doctor immediately for treatment advice.✓Have person sip a glass of water if able to swallow.✓Do not induce vomiting unless told to do so by a poison control center or doctor.✓Do not give anything by mouth to an unconscious person.✓
If inhaled	<ul style="list-style-type: none">Move person to fresh air.✓If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.✓Call a poison control center or doctor for further treatment advice.✓
If on skin or clothing	<ul style="list-style-type: none">Take off contaminated clothing.✓Rinse skin immediately with plenty of water for 15-20 minutes.✓Call a poison control center or doctor for treatment advice.✓
If in eyes	<ul style="list-style-type: none">Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.✓Call a poison control center or doctor for treatment advice.✓

FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL THE NATIONAL PESTICIDE
INFORMATION CENTER 1-800-858-7378 ✓

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning

May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. *Add Derm. Sens. Statement*

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer.

systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency. ✓

Physical/Chemical Hazards ✓

Do not use or store near heat or open flame. ✓

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. ✓

This material requires further mixing before use ✓

Only for formulation into an insecticide/miticide for

(1) The following uses:

~~Terrestrial Food/Feed Crops: Sweet Corn, Succulent Peas and Beans, Head and Stem Brassica Vegetables, Globe Artichoke, Cucurbits, Herbs, Bananas (import only), Legume Vegetables, Cotton, Field Corn (Grain and Silage), Popcorn, Field Corn Grown for Seed, Hops, Greenhouse Grown Ornamental Trees, Shrubs, Plants, Flowers, Non-bearing Fruit and Nut Trees, Rapeseed, Canola, Cranberries, Strawberries, Raspberries, Lettuce (head), Pears, Citrus, Tomato, Peppers (bell and non-bell), Eggplant, Spinach, Tree Nuts.~~

*
could
add
grapes

Terrestrial Non-Food:

Termite and Soil Contact Nonfumigation Treatment ✓

Wood Treatment and Protection ✓

Outdoor Insect Control ✓

Ornamental plants, trees, shrubs, and vines (woody) ✓

Residential Lawns ✓

Indoor Insect Control ✓

move

Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling). ✓

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where foods may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (canning, bottling, wrapping, boxing), preparing, edible wastes, storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered a food area. ✓

(2) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and ✓

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements. ✓

Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label. ✓

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

EPA Approved. 08/25/2003
Revision (notification): 09/05/2003
Draft Amendment: 10/02/2003

3 Guidelines not cited
on matrix

Required

Required:
not cited

§ 158.949 Residue chemistry data requirements.

(a) Table. Sections 158.90 and 158.100 through 158.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Sub- stance reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to sup- port MP	Data to sup- port EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Chemical identity _____	(1)	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	TGAJ _____	TGAJ _____	171-3
Directions for use _____	(2)	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]			171-3
Nature of the residue:													
Plants _____	(13), (14)	[P]		[P]		[P]			[CP]	[CP]	PAIRA _____	PAIRA _____	171-4
Livestock _____	(3), (13), (14)	[CP]		[CP]		[CP]			[CP]	[CP]	PAIRA and plant metabolites	PAIRA and plant me- tabolites	171-4
Residue analytical method _____	(4), (13), (14), (15)	[P]		[P]		[P]			[CP]	[CP]	TGAJ and me- tabolites	TGAJ and me- tabolites	171-4
Magnitude of the re- sidue:													
Crop field trials _____	(13), (14)	[P]		[P]		[P]			[CP]	[CP]	TEP _____	TEP _____	171-4
Processed food/ feed _____	(8), (14)	[CP]		[CP]		[CP]				[CP]	EP _____	EP _____	171-4
Meat/fat/poultry/ eggs _____	(8), (14)	[CP]		[CP]		[CP]				[CP]	TGAJ or plant metabolites	TGAJ or plant metabolites	171-4
Potable water _____	(7)			[P]							EP _____	EP _____	171-4
Fish _____	(9)			[P]	[CP]						EP _____	EP _____	171-4
Irrigated crops _____	(10)			[P]							EP _____	EP _____	171-4
Food handling _____	(10), (14)									[CP]	EP _____	EP _____	171-4
Reduction of residue _____	(11), (14)	[CP]		[CP]		[CP]				[CP]	Residue of concern	Residue of concern	171-5
Proposed tolerance _____	(12), (14)	[P]		[P]		[P]				[CP]	Residue of concern	Residue of concern	171-6
Reasonable grounds in support of the petition _____	(14)	[P]		[P]		[P]				[CP]			171-7
Submittal of analytical reference standards _____	(14)	[P]		[P]		[P]				[CP]	PAIRA _____	PAIRA _____	171-13

Key: P-Required data; CP-Conditionally required data; TGAJ-Technical grade of the active ingredient; PAIRA-Pure active ingredient, radio labeled; EP-End-use product; TEP-Typical end-use product; MP-Manufacturing-use product; []-Brackets (P, CP, [CP]) indicate data requirements that apply when an experimental use permit is being sought.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

- (1) The same chemical identity data as required under subpart C of this part are required, with emphasis on impurities that could constitute a residue problem.
- (2) Required information includes crop to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.
- (3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.
- (4) A residue method for enforcement of tolerances is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.
- (5) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

- (10) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.
- (11) Data on residues in public water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used for drinking purposes, by man or animals.
- (12) Data on residues in fish are required whenever a pesticide is to be applied directly to water labeled for fish.
- (13) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or in irrigation facilities such as irrigation ditches.
- (14) Data on residues in food crops in food handling establishments are required whenever a pesticide is to be used in food handling establishments. Pesticides and conditions used in food or food handling establishments are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 170.102.
- (15) Evaluation of residue data are required when the accumulation of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in cases where data are revealed which indicate the pesticide in food levels than initially determined.
- (16) The proposed tolerance must reflect the maximum residue likely to occur in crops and manure/poultry eggs.
- (17) Pesticide data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerance was established.
- (18) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.
- (19) For all food uses, data on whether the FDA/USDA methodology would detect and identify the pesticide are required.

(40 FR 42821, Oct. 24, 1964. Redesignated and amended at 53 FR 15933, 15939, May 4, 1988; 53 FR 24203, June 23, 1988)

§ 158.230 Environmental fate data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the environmental fate data requirements and the substance to be tested.

Kind of data required	(B) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MEP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Degradation studies-lab													
Hydrolysis		PR	PR	PR	PR	PR	PR	PR	PR		TGAJ or PAIRA	TGAJ or PAIRA	158-1
In water		R	R	R	R			R			TGAJ or PAIRA	TGAJ or PAIRA	158-2
In soil	(1)	CR						CR			TGAJ or PAIRA	TGAJ or PAIRA	158-3
In air	(2)	CR									TGAJ or PAIRA	TGAJ or PAIRA	158-4
Metabolism studies-lab													
Aerobic soil		PR	PR			R	R	PR	R		TGAJ or PAIRA	TGAJ or PAIRA	158-5
Anaerobic aquatic				R	R			R			TGAJ or PAIRA	TGAJ or PAIRA	158-6
Aerobic aquatic				PR	PR						TGAJ or PAIRA	TGAJ or PAIRA	158-7

Mutagenicity studies													
Leaching and absorption studies		PR	PR	R	R	R	R	PR	R		TGAJ or PAIRA	TGAJ or PAIRA	158-8
Field	(3)	CR				CR	CR				TEP	TEP	158-9
Dispersion studies-field													
Soil		R	R								TEP	TEP	158-10
Aquatic (sediment)				R	R				R		TEP	TEP	158-11
Forestry								R			TEP	TEP	158-12
Combination and tank mixes	(4)	CR		CR							TEP	TEP	158-13
Soil, long-term													
Accumulation studies													
Perennial crops	(5)	ICR		ICR							PAIRA	PAIRA	158-14
Annual crops	(6)	CR		CR							TEP	TEP	158-15
Ornamental plants	(7)	ICR		ICR							TEP	TEP	158-16
In fish	(8)	ICR	ICR	ICR	ICR			ICR			TGAJ or PAIRA	TGAJ or PAIRA	158-17
In aquatic non-target organisms	(9), (10)							CR			TEP	TEP	158-18

Key: PR=Required; CR=Conditionally required; []=Bracketed (e.g., PR, ICR) indicates data requirements that apply when an experimental use permit is being sought; TGAJ=Technical grade of the active ingredient; PAIRA="Pure" active ingredient; TEP=typical and use product; EP=final use product.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

AAA(2) Required on cases by case basis depending on product use pattern and other pertinent factors.

AAA(3) Not required if anaerobic aquatic metabolism study has been conducted.

AAA(4) Required if pesticide residues do not readily dissipate in soil.

AAA(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

AAA(6) Field accumulation study is required if significant pesticide residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

AAA(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

AAA(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

AAA(9) Required unless tolerance or action level for fish has been granted.

(40 FR 42821, Oct. 24, 1964. Redesignated at 53 FR 15933, May 4, 1988)

§ 158.340 Toxicology data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

161-3 Required and submitted by FMC. Must cite.

163-2

100

100

101

Kind of data required	(a) Tests	General use pesticides										Test substance		Substance reference file
		Terrestrial		Aquatic		Greenhouse		Forest	Domestic outdoor	Indoor	Data to support MP	Data to support EP		
		Food crop	Nonfood	Food crop	Nonfood	Plant crop	Nonfood							
Acute testing														
Acute oral toxicity—rat	(1)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGA	EP or EP studies and TGA		
Acute dermal toxicity	(1), (5)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGA	EP or EP studies and TGA		
Acute inhalation toxicity—rat	(3)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGA	EP and TGA		
Primary eye irritation—rabbit	(2)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP	EP		
Primary dermal irritation	(1), (2)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP	EP		
Dermal sensitization	(4)	PI	PI	PI	PI	PI	PI	PI	PI	PI	TGA	TGA		
Subchronic testing														
90-day feeding studies—rodent and nonrodent	(17)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA and EP		
90-day dermal	(18), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
90-day inhalation—rat	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
90-day neurotoxicity	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Non-rodent	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Chronic testing														
Chronic feeding—2 spp. rodent and nonrodent	(21), (22)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Oncogenicity study—2 spp. rat and mouse preferred	(21), (22)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Yeast mutagenicity—2 species	(18), (19)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Microbial mutagenicity—2 species	(18), (19)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Mitogenicity testing														
Gene mutation	(22)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Structural chromosomal aberration	(22)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		
Other genetic effects	(22)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGA	TGA		

Special testing

General metabolism	(23)	PI	CR	CR	CR	CR	CR	CR	CR	CR	PI or FAFRA Choice	PI or FAFRA Choice	
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	
Domestic animal safety	(12)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	

Key: PI—Required data; CR—Conditionally required; ()—Indicates data requirements that apply when an experimental use permit is being sought; MP—Minimum required use product; EP—End-Use Product; (asterisk) identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source; TGA—Technical grade of the active ingredient; PAI—Pure active ingredient; FAFRA—Pure active ingredient, non-labeled; Choice—Choice of several test substances, depending on studies required.

- (a) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
- (1) Not required if test material is a gas or highly volatile.
 - (2) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as toxicity category I on the basis of potential eye and dermal irritation effects.
 - (3) Required unless repeated dermal exposure does not occur under conditions of use.
 - (4) Not required unless test material is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.
 - (5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.
 - (6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.
 - (7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.
 - (8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.
 - (9) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.
 - (10) Minimum acceptable test duration for chronic feeding and oncogenicity studies are as follows:
 - Chronic rodent feeding study (food use pesticides)—24 months.
 - Chronic rodent feeding study (non-food pesticides)—18 months is usually sufficient.
 - Chronic nonrodent (i.e., dog) feeding study—12 months.
 - Mouse oncogenicity study—18 months.
 - Rat oncogenicity study—24 months.
 - (11) Required to support products intended for food use and to support products intended for non-food use if significant exposure of human females of child bearing age may reasonably be expected.
 - (12) Required to support products intended for food use and to support products intended for non-food use if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, pesticides used in treated lawns for mowing, spraying, or feeding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in several forms).
 - (13) Required on a case by case basis.
 - (14) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feeding study is required to support a temporary tolerance.
 - (15) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.
 - (16) A toxicology study in one species is required to support a temporary tolerance.
 - (17) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particles).
 - (18) Required if intended use of the pesticide product is expected to result in human exposure to the product, under the following conditions:
 - Human exposure is via the oral route.
 - Expected human exposure is over a linked portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).
 - Required if intended use of the pesticide product is expected to result in human exposure to the product, under the following conditions:
 - Human exposure is via skin contact.
 - Expected human skin contact is not purposeful, and such exposure is of limited frequency and duration (for example, such exposure could result from use of certain disinfectant, liquid hand soap or agricultural or household pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).
 - (19) Data from a subchronic 90-day dermal toxicity study are not required.
 - (20) Required if pesticide use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing, and if either of the following criteria are met:
 - Data from a subchronic oral study are not required.
 - The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.
 - (21) Required if either of the following criteria are met:
 - Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).

- (3) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires tolerance of a food additive regulation.
- (4) Required if any of the following criteria are met:
- The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
 - is structurally related to a recognized carcinogen.
 - is a substance that causes mutagenic effect as demonstrated by *in vivo* or *in vitro* testing.
 - Produces in subchronic studies a neoplastic effect (e.g., hyperplasia, dysplasia) in any organ that may lead to neoplastic changes.
- (5) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
- (6) The use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example, pesticides used in treated food for serving appetizers, desserts, or beverages; insect repellents applied directly to human skin; swimming pool additives; consumer products; and pesticides which are used in animal feed).
- (7) The required history of toxicological tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 158.102:
- Genotoxicity.
 - Structural chromosomal alterations.
 - Other genotoxic effects or appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.

(8) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the history of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency, test selection, protocol design and results of preliminary testing.

(9) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed ball rooms).

(10) Required if chronic feeding or chronic toxicity studies are required.

(11) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the absorption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15003, May 4, 1988; 58 FR 54203, June 23, 1993]

§ 158.290 Reentry protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support ED ^a	Data to support EP ^a	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Feder distribution _____	(1)	CR	CR	CR	CR	_____	_____	CR	_____	_____	TEP _____	TEP _____	201-1
Self distribution _____	(1), (4)	CR	CR	CR	CR	_____	_____	CR	_____	_____	TEP _____	TEP _____	
Dermal exposure _____	(1), (2), (3)	CR	CR	CR	CR	_____	_____	CR	_____	_____	TEP _____	TEP _____	
Inhalation exposure _____	(1), (2), (3)	CR	CR	CR	CR	_____	_____	CR	_____	_____	TEP _____	TEP _____	

Key: CR=Conditionally required; TEP=Typical end-use product.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

- Data are required if the following conditions are met:
- (1) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg body weight; or
- (2) The acute inhalation toxicity of the technical grade of active ingredient is less than 500 mg/m³ for a one-hour exposure; or
- (3) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg body weight; or
- (4) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from any of persons who handled the pesticide.
- The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
- And if end-use product is to be registered for:
- Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.

- Application to building site cleanup and forestry operations.
- Application to turf crops and commercial applications to turf.
- Application to parks and recreational; or (2) application to aquatic crops.
- And if human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
- Data required if appropriate surrogate data are not available.
- Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
- Soil desorption data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15003, May 4, 1988, and amended at 58 FR 54203, June 23, 1993]

§ 158.440 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Guideline reference No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support EP		Data to support EP
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum	(1)	CR	CR	CR	CR			CR			TEP	TEP	201-1 200
Drift field evaluation	(1)	CR	CR	CR	CR			CR			TEP	TEP	

Key: CR=Conditionally required; TEP=Typical and use product.

(b) NOTES.— The following are not to be used in the evaluation of the pesticide:

Key: CR=Conditionally required; TEP=Typical end-use product.

(b) Notes.—The following are referenced in column two of the table contained in paragraph (a) of this section.

- This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submission of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
- [Reserved]

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15003, May 4, 1988, and amended at 58 FR 54203, June 23, 1993]

§ 158.490 Wildlife and aquatic organisms data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support EP	Data to support EP		
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood							
Avian and mammalian testing														
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1)	[P]	[P]	[P]	[P]	CR	CR	[P]	[P]	CR	TGAJ _____	TGAJ _____	75-1	

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Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support LEP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	PI	PI	PI	PI	CR	CR	PI	PI	CR	TGAJ	TGAJ	71-6
Wild mammal toxicity.	(2)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-6
Avian reproduction (preferably mallard and bobwhite).	(2)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-6
Estimated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR			CR	CR		TEP	TEP	71-6
Aquatic organisms testing.	(1), (7)	PI	PI	PI	PI	CR	CR	PI	PI	CR	TGAJ	TGAJ	71-6
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	PI	PI	PI	PI	CR	CR	PI	PI	CR	TGAJ	TGAJ	71-6
Aquatic LC ₅₀ freshwater invertebrates (preferably Daphnia).	(4), (7)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-6
Aquatic LC ₅₀ sediments and marine organisms.	(3)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-6
Fish early life stage and aquatic invertebrate life-cycle.	(3)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-6
Fish—life cycle.	(3)	CR	CR	CR	CR			CR	CR		TGAJ, PAL, or degradation product.	TGAJ, PAL, or degradation product.	72-6
Aquatic organism accumulation.	(3)	CR	CR	CR	CR			CR	CR		TEP	TEP	72-7
Estimated or actual field testing—organisms.	(3)	CR	CR	CR	CR			CR	CR		TEP	TEP	72-7

Key: PI=Required; CR=Conditionally required; _____=Excluded. (a) PI, CR, and _____ indicate data requirements that apply when an experimental use permit is being sought; TGAJ=Technical grade of the active ingredient; TEP=Typical end-use product; PAL=Pure active ingredient.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product: (A) Data from fish early life stage and life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply: (i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. (ii) If any LC₅₀ or EC₅₀ value determined in acute toxicity testing is less than 1 mg/L; or (iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing. (B) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist: (i) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected. (ii) Physicochemical properties indicate cumulative effects. (iii) The pesticide is persistent in water (e.g., half-life in water greater than 4 days). (iv) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply: (i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test. (ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide. (iii) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions: (i) The end-use pesticide will be introduced directly into an aquatic environment when used as directed. (ii) The LC₅₀ or EC₅₀ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed. (iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms. (iv) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

(3) Data required if one or more of the following criteria are met:

- (a) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
 - (b) The pesticide or any of its major metabolite or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian food.
 - (c) The pesticide or any of its major metabolite or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol-water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
 - (d) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.
- NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.
- (4) Data required if the product is intended for direct application to the aquatic or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.
- (5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:
- (i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
 - (ii) If any LC₅₀ or EC₅₀ value determined in acute toxicity testing is less than 1 mg/L; or
 - (iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing.
- (6) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist:
- (i) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
 - (ii) Physicochemical properties indicate cumulative effects.
 - (iii) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
- (7) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:
- (i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
 - (ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.
 - (iii) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions: (i) The end-use pesticide will be introduced directly into an aquatic environment when used as directed. (ii) The LC₅₀ or EC₅₀ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed. (iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms. (iv) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

[40 FR 42831, Oct. 24, 1964. Redesignated at 53 FR 15893, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.540 Plant protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity	(1)	_____	_____	_____	_____	_____	_____	_____	_____	_____	EP _____	EP _____	121-1
Non-target area phytotoxicity	(1)	_____	_____	_____	_____	_____	_____	_____	_____	_____	EP _____	EP _____	121-1
Tier I: Seed germination/ seedling emergence	(2)	_____	R	_____	R	_____	_____	R	_____	_____	TGAJ _____	TGAJ _____	122-1
Vegetative vigor	(2)	_____	R	_____	R	_____	_____	R	_____	_____	TGAJ _____	TGAJ _____	122-1

Kind of data required	(a) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Aquatic plant growth	(2)		R		R			R			TGA	TGA	123-2
Tier II: Seed germination/ seedling emergence	(2)		CR		CR			CR			TGA	TGA	123-1
Vegetative vigor	(3)		CR		CR			CR			TGA	TGA	123-1
Aquatic plant growth	(4)		CR		CR			CR			TGA	TGA	123-2
Tier II: Terrestrial field	(5)		CR		CR			CR			TEP	TEP	124-1
Aquatic field	(6)		CR		CR			CR			TEP	TEP	124-2

Key: CR—Conditionally required; TGA—Technical grade of the active ingredient; EP—End-use product; TEP—Typical end-use product.
 (1) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
 (2) Data are required for Special Review and certain public health situations.
 (3) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation, the aquatic plant growth tests will be required. Data are required to support products to be used in other locations where any of the following conditions are met:
 (a) Physiological problems concerning the product arise and open literature data are not available to address the problem.
 (b) The product may pose hazards to endangered or threatened species.
 (c) Special Review has been initiated on the product.
 (4) Required if a 50 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.
 (5) Required if a 50 percent or greater detrimental effect was found in any plant species in the corresponding test of the previous tier.
 (6) Required if a 50 percent or greater detrimental effect was found in any plant species in the corresponding test of the previous tier.

[40 FR 42831, Oct. 24, 1974. Redesignated at 53 FR 15293, May 4, 1988, and amended at 55 FR 34203, June 23, 1990]

§ 158.550 Nontarget insect data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.162 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

Kind of data required	(a) Notes	General use pattern									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect testing—pollinators											TGA	TGA	141-1
Honey bee acute contact LD ₅₀	(1)	CR	CR	CR	CR			CR	CR		TEP	TEP	141-2
Honey bee—tactility of residues on foliage	(1), (2)	CR	CR	CR	CR			CR	CR				141-3
Honey bee subacute feeding study	(3)												141-4
Field testing for pollinators	(4)	CR	CR	CR	CR			CR	CR		TEP	TEP	141-5

Nontarget insect testing—aquatic insects	(5)												142-1
Acute toxicity to aquatic insects	(5)												142-1
Aquatic insect life-cycle study	(5)												142-2
Stratified or actual field testing for aquatic insects	(5)												142-1
Nontarget insect testing—predators and parasites	(5)												142-2

Key: CR—Conditionally required; []—Bracketed (e.g., [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; TGA—Technical grade of the active ingredient; TEP—Typical end-use product.
 (1) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
 (2) Required only if proposed use will result in honey bee exposure.
 (3) Required only when formulation contains one or more active ingredients having an acute LD₅₀ of less than 1 microgram/bee.
 (4) This requirement is reserved pending development of test methodology.
 (5) May be required under the following conditions:
 (a) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).
 (b) Data from acute toxicity studies indicate substantial residual toxicity.
 (c) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.
 (6) This requirement is reserved pending further evaluation in determining what and when data should be required, and to develop appropriate test methods.

[40 FR 42831, Oct. 24, 1974. Redesignated at 53 FR 15293, May 4, 1988, and amended at 55 FR 34203, June 23, 1990]

§ 158.540 Product performance data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.162 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)									CR		EP	91-2
Products requiring contact data.	(1)									CR		EP	91-3
Products for use on fabrics and linoleum.	(1)									CR		EP	91-4
Air sanitizers	(1)									CR		EP	91-5
Products for control of microbial pests associated with human and animal wastes.	(1)									CR		EP	91-7

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Kind of data required	(2) Notes	General use patterns									Test substances		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Products for treating water systems.	(1)			[CR]						CR		EP	81-4
Efficacy of fungicides and nematocides													
Products for control of organisms producing mycotoxins.	(1)	[CR]		[CR]		[CR]						EP	83-18
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	[P]	[P]						[P]	[P]		EP	88-6
Avian repellants	(1)	[P]	[P]						[P]	[P]		EP	88-6
Avian frightening agents	(1)	[P]	[P]						[P]	[P]		EP	88-7
Bat toxicants and repellants.	(1)									[P]		EP	88-6
Commercial rodenticides	(1)	[P]	[P]						[P]	[P]	TEP	EP	88-10
Rodenticides on farm and rangelands.	(1)	[P]	[P]						[P]	[P]		EP	88-12
Rodent fumigants	(1)	[P]	[P]						[P]	[P]		EP	88-13
Rodent reproductive inhibitors.	(1)	[P]	[P]						[P]	[P]		EP	88-16
Mammalian pesticides	(1)	[P]	[P]						[P]	[P]		EP	88-17

Key: P=Required; CR=Conditionally required; []=Bracketed (i.e., [P], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; EP=end-use product (technical identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source; MP=Manufacturing use product; TEP=Typical end-use product.

(2) Notes: The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.
(1) The Agency has waived all requirements to submit efficacy data where the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms hazardous to man in any area of the landscape environment or a claim to control vertebrates (such as rodents, birds, bats, snakes, and alligators) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.
(2) [Reserved]

[49 FR 42381, Oct. 24, 1984, as amended at 50 FR 46708, Nov. 13, 1985. Redesignated at 53 FR 15583, May 4, 1988, and amended at 59 FR 34303, June 23, 1993]

§ 158.650 Biochemical pesticides data requirements.

(a) Biochemical pesticide product analysis data requirements—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—product analysis data requirements and the

Kind of data required	(2) Notes	General use patterns									Test substances		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product Identity	(1)	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	MP	EP	151-10
Manufacturing process	(1)	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	MP and TGA	EP and TGA	151-11
Discussion of formation of unintentional ingredients.	(1)	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	MP and TGA	EP and TGA	151-12
Analysis of samples	(1)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGA	EP and TGA	151-13
Certification of limits			R		R			R	R	R	MP	EP	151-15
Analytical methods		[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	MP and TGA	EP and TGA	151-16
Physical and chemical properties.		[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	[P]	MP and TGA, PAL	EP, TGA and PAL	151-17
Substrate of samples	(1)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			151-18

Key: R-Required CR-Conditionally required; MP-Manufacturing-use product; EP-End-use product (consumer use); must actively provide the data.

Key: P=Required; CR=Conditionally required; MP=Manufacturing use product; EP=end-use product (technical identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source; TGA=Technical grade of the active ingredient; []=Bracketed (i.e., [P], [CR]) indicates data requirements that apply when an experimental use permit is being sought.

(2) Notes: The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.
(1) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.
(2) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.
(3) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) Biochemical pesticides residue data requirements. (1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—residue data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substances		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Chemical identity _____	(1), (2), (3a)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGA	TGA	153-3
Directions for use _____	(1), (2), (3a)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	_____	_____	153-3
Nature of the residue:													
Plants _____	(1), (3a)	[CR]	_____	[CR]	_____	[CR]	_____	_____	_____	_____	PAIRA _____	PAIRA _____	153-3
Livestock _____	(1), (3a)	[CR]	_____	[CR]	_____	[CR]	_____	_____	[CR]	_____	PAIRA and plant metabo- _____	PAIRA and plant metabo- _____	153-3



United States
Environmental Protection Agency
Washington, DC 20460

Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70506-18	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bifenthrin Technical Insecticide/Miticide	PM # 13	
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. 279-3055 Product Name Bifenthrin Technical Insecticide/Miticide	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input checked="" type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Amend label to add food/feed uses

Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		II "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		II "Yes" Package wgt	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
3. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Elizabeth Anne Brown	Title ChemReg International, LLC Authorized agent	Telephone No. (Include Area Code) 703-492-7905
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Elizabeth Anne Brown</i>	3. Title ChemReg International, LLC Authorized Agent	
4. Typed Name Elizabeth Anne Brown	5. Date October 6, 2003	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

United Phosphorus, Inc.

423 Riverview Plaza

Trenton, NJ 08611

609-392-8200

EPA Registration Number/File Symbol

70506-18

Active Ingredient(s) and/or representative test compound(s)
 bifenthrin

Date

October 6, 2003

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Terrestrial Non-Food, Domestic Outdoor, Indoor, Terrestrial Food/Feed

Product Name

Bifenthrin Technical Insecticide/Miticide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-in response is supported by all data submitted or cited in a application for registration, the form for reregistration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature

Ann M. Tillman

Date

Oct. 6, 2003

Typed or Printed Name and Title

Ann M. Tillman
 Technical Director



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 10, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ELIZABETH ANNE BROWN
UNITED PHOSPHORUS INC
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

PRODUCT NAME: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE
COMPANY NAME: UNITED PHOSPHORUS INC
EPA FILE SYMBOL: 70506-18
EPA RECEIPT DATE: 10/06/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 305-6788.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. Wrice".

Front End Processing Staff
Information Services Branch
Information Resources and Services Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 1 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product: Bifenthrin Technical Insecticide/Miticide
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1 (830.1550)	Chemical identity	45654401	United Phosphorus Inc (UPI)	Own	
61-2a (830.1620)	Starting materials and manufacturing process	45654401	UPI	Own	
61-2b (830.1670)	Formation of impurities	45654401	UPI	Own	
62-1 (830.1700)	Preliminary analysis	45654401	UPI	Own	
62-2 (830.1750)	Certification of limits	45654401	UPI	Own	
62-3 (830.1800)	Analytical method	45654401	UPI	Own	
63-2 (830.6302)	Color	45654402	UPI	Own	
63-3 (830.6303)	Physical state	45654402	UPI	Own	
63-4 (830.6304)	Odor	45654402	UPI	Own	
None (830.7050)	UV/Visible Absorption	CITE ALL	FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
63-5 (830.7220)	Melting point	45838001	UPI	own	
63-7 (830.7300)	Density	45838001, 46008501, 46008502	UPI	own	
63-8 (830.7840)	Solubility	CITE ALL	FMC, Scotts, Andersons	pay	
63-9 (830.7950)	Vapor pressure	CITE ALL	FMC, Scotts, Andersons	Pay	
63-10 (830.7370)	Dissociation constant	CITE ALL	FMC, Scotts, Andersons	Pay	
63-11 (830.7550)	Octanol/water partition	CITE ALL	FMC, Scotts, Andersons	Pay	
63-12 (830.7000)	pH	45838001	UPI	own	
63-13 (830.6313)	Stability	45654403	UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 2 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product: Bifenthrin Technical Insecticide/Miticide
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314 ✓	Oxidation/reduction	45838001	UPI	Own	
830.6315 ✓	Flammability	45838001	UPI	Own	
830.6316 ✓	explosibility	45838001	UPI	Own	
830.7220 ✓	Boiling point	45838001	UPI	Own	
830.7370 ✓	Dissociation constant	45838001	UPI	own	
71-1b (850.2100) ✓	Avian acute oral toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-2 (850.2200) ✓	Avian dietary toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-4 (850.2300) ✓	Avian reproduction	CITE ALL	FMC, Scotts, Andersons	Pay	
72-1 (850.1075) ✓	Fish acute toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-2 (850.1010) ✓	Invertebrate toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-3 (850.1025 - 1055) ✓	Estuarine/marine toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1300) ✓	Invertebrate Chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1350) ✓	Invertebrate chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-5 (850.1400) ✓	Fish life early life cycle	CITE ALL	FMC, Scotts, Andersons	Pay	
141-1 (850.3020) ✓	Honeybee acute contact toxicity	CITE ALL	FMC, Scotts, Andersons	pay	
81-1 (870.1100) ✓	Acute oral - rat	45654404	UPI	Own	
81-2 (870.1200) ✓	Acute dermal - rabbit/rat	45645505	UPI	Own	
81-3 (870.1300) ✓	Acute inhalation - rat	00155286	FMC	Old	
81-4 (870.2400) ✓	Primary eye irritation - rabbit	00132522	FMC	Old	
81-5 (870.2500) ✓	Primary dermal irritation - rabbit	00132521	FMC	Old	
81-6 (870.2600) ✓	Dermal sensitization	00132523	FMC	Old	
81-8 (870.6200) ✓	Acute neurotoxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
82-1 (870.3100) ✓	90-Day feeding	CITE ALL	FMC, Scotts, Andersons	pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 3 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-2 (870.3200) ✓	21-Day dermal toxicity – rats	CITE ALL	FMC, Scotts, Andersons	Pay	
82-7 (none) ✓	Subchronic neurotoxicity – rat	CITE ALL	FMC, Scotts, Andersons	pay	
83-1a (870.4100) ✓	Chronic feeding toxicity – rodent	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-1b (870.4100) ✓	Chronic feeding toxicity – dog	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2a (870.4200) ✓	Oncogenicity – rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2b (870.4200) ✓	Oncogenicity – mouse	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3a (870.3700) ✓	Teratogenicity – rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3b (870.3700) ✓	Teratogenicity – rabbit	CITE-ALL	FMC, Scotts, Andersons	Pay	
OPPTS 870.6300 ✓	Developmental Neurotoxicity	Data gap			
84-2 ✓	Mutagenicity studies	CITE-ALL	FMC, Scotts, Andersons	Pay	
84-4 ✓	Other genotoxic effects	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-1 (870.7485) ✓	General metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-2 ✓	Dermal absorption	CITE-ALL	FMC, Scotts, Andersons	Pay	
161-1 ✓	Hydrolysis	CITE ALL	FMC, Scotts, Andersons	Pay	
161-2 ✓	Photodegradation in water	CITE ALL	FMC, Scotts, Andersons	Pay	
162-1 ✓	Aerobic soil metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
163-1 ✓	Adsorption/desorption	CITE ALL	MC, Scotts, Andersons	Pay	
164-1 (875.2200) ✓	Field soil dissipation	CITE-ALL	FMC, Scotts, Andersons	Pay	
165-4 ✓	Bioaccumulation in fish	CITE-ALL	FMC, Scotts, Andersons	pay	
Special studies ✓	Other	CITE ALL	Pyrethroid Working Group	pay	
132-1 (857.2100) ✓	Foliar residue dissipation	CITE ALL	FMC, Scotts, Andersons	Pay	

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Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 4 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
133-3 (875.2400, 2500) ✓	Dermal exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
133-4 (857.2500) ✓	Inhalation exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
201-1, 202-1 (840.1100, 835.4200) ✓	Spray drift and droplet size	CITE ALL	UPI is a member of the Spray Drift Task Force	Own	
171-4a	Nature of residue – plants	CITE ALL	FMC	Pay	
171-4b	Nature of residue – livestock	CITE ALL	FMC	Pay	
171-4c	Residue analytical method – plants	CITE ALL	FMC	Pay	
171-4d	Residue analytical method – animals	CITE ALL	FMC	Pay	
171-4e	Residue storage stability	CITE ALL	FMC	Pay	
171-4j ✓	Magnitude of residues – meat/milk/poultry/egg	CITE ALL	FMC	Pay	
171-4k	Magnitude of residues – field crop trials	CITE ALL	FMC, IR-4	Pay	
171-4l	Magnitude of residues – processed commodities	CITE ALL	FMC	Pay	
171-4m	Multi-residue method	CITE ALL	FMC	Pay	
165-1 ✓	Confined rotational crop	CITE ALL	FMC	Pay	
165-2 ✓	Field rotational crop	CITE ALL	FMC	Pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemRcg International, LLC Registration Agent	Date 9/17/2003
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401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 1 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Treaton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			United Phosphorus Inc (UPI)	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
			UPI	own	
			UPI	own	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			UPI	own	
			UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 2 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	own	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			UPI	Own	
			UPI	Own	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 3 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			MC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			Pyrethroid Working Group	pay	
			FMC, Scotts, Andersons	Pay	

65

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 9/17/2003
--	--	-------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: September 17, 2003	EPA Reg No./ File Symbol 70506-18	Page 4 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Milicide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Spray Drift Task Force	Own	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC, IR-4	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	
			FMC	Pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

9/17/2003



1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

September 5, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Ms. Sherada Hobgood

Re: Notification of Other Labeling Revisions. Bifenthrin Technical Insecticide/Miticide,
EPA Reg. No. 70506-18

Dear Sherada:

On behalf of our client, United Phosphorus, Inc., we are notifying for a change in the medical emergency contact phone number and the warranty statement for the above product. This submission is under the notification procedure, as identified in PR Notice 98-10.

As required by PR Notice 98-10 for notifications, enclosed please find the following:

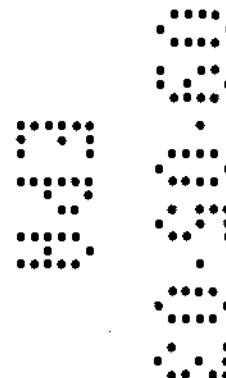
1. Application Form (8570-1)
2. One copy of the product labeling with changes highlighted.

Please let me know if you have any questions about the enclosed items.

Regards,

Elizabeth Anne Brown
Elizabeth Anne Brown

cc: United Phosphorus, Inc.



CONSULTANTS TO SUCCESSSM

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



1990 OLD BRIDGE ROAD, SUITE 201
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www.pesticide.net

ELIZABETH A. BROWN, PH.D.

October 6, 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Mr. George LaRocca (PM 13)

Re: Application for Label Amendment. Bifenthrin Technical Insecticide/Miticide, EPA Reg. No. 70506-18

Dear George:

On behalf of our client, United Phosphorus, Inc., enclosed please find an application to amend the label for the above product. This amendment is to add food crop uses, identical to those registered for the substantially similar product EPA Reg. No. 279-3055 (approval date 5/7/2003).

Enclosed with this application please find:

1. EPA Form 8570-1, Application
2. EPA Form 8570-34, Certification with Respect to Citation of Data
3. EPA Form 8570-34, Public File and Agency Use copies
4. Five (5) copies of the amended labeling, with one copy highlighted to show the changes,

Please let me know if you have any questions or if anything further is needed.

Regards,

Elizabeth Anne Brown

cc: United Phosphorus, Inc.

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Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning: May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters areas in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewer treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This material requires further mixing before use.

Only for formulation into an insecticide/miticide for

Terrestrial Non-Food:

Formulation and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Residential Lawns

Indoor Insect Control

Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, laboratories, floor drains (no sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after cleaning and bolting).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas where food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where food may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (packing, loading, wrapping, boxing), preparing, eating, storage and enclosed processing systems (mills, dairies, cotton oil, etc.). Serving areas (when food is exposed and facility is in operation) also would be considered a food area.

(g) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

(f) Uses for experimental purposes that are in compliance with U.S. EPA requirements. Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

BIFENTHRIN Technical

Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin (S-methyl 1:1-Isomers) (3-Phenyl-2-methyl-3-(4-chlorophenyl)-3,3-difluoro-1-propenyl)-2,2-dimethylpropanecarboxylates 98.4%

OTHER INGREDIENTS 0.6%

TOTAL 100.0%

*Ca borates 87% minimum, trace borates 5% maximum.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.

- Have person sip a glass of water if able to swallow.

- Do not induce vomiting unless told to do so by a poison control center or doctor.

- Do not give anything by mouth to an unconscious person.

If inhaled:

- Move person to fresh air.

- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

- Call a poison control center or doctor for further treatment advice.

If on skin or clothing:

- Take off contaminated clothing.

- Rinse skin immediately with plenty of water for 15-20 minutes.

- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.

- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

- Call a poison control center or doctor for treatment advice.

FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL

THE NATIONAL PESTICIDE INFORMATION CENTER 1-800-858-7378

FOR CHEMICAL EMERGENCY: spill, leak, fire, exposure, or accident call

CHEMTREC 1-800-424-9300

United Phosphorus Inc.

423 Riverview Plaza

Truiston, NJ 08611

NET CONTENTS:

EPA Reg. No. 70505-18

EPA Est. No. 41676-N-1

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrates or dilute material into food or drink containers. Do not combine with other pesticides, fertilizers, water, food, or feed by storage or disposal. In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Contain spills.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or residue is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty lines by shaking and tapping sides and bottom to loosen clinging particles. Empty residual into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

CONDITIONS OF SALE

AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey title hereto, and that each product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

03/25/2003

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning: May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This material requires further mixing before use.

Only for formulation into an insecticide/miticide for

Terrestrial Non-Food:

Termite and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Ornamental plants, trees, shrubs, and vines (woody)

Residential Lawns

Indoor Insect Control

Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after cleaning and bolting).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where food may be prepared or held in the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for roasting, storage/buckling (canning, bottling, wrapping, bagging), preparing, eating, eating, storage and enclosed processing systems (mills, dairies, oil, etc.). Spills, dripping areas (when food is exposed and facility is in operation) also would be considered a food area.

Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

Uses for experimental purposes that are in compliance with U.S. EPA requirements. Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

BIFENTHRIN Technical

Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin (2-methyl-1,1-diphenyl-3-(2-chlorophenyl)-2-propenyl) 99.4%

OTHER INGREDIENTS

2,2-dimethyl-1,3-dioxane-5-carboxylic acid 0.6%

TOTAL

100.0%
*Cis isomers 97% minimum, trans isomers 3% maximum.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.

FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL
THE NATIONAL PESTICIDE INFORMATION CENTER 1-800-858-7378

FOR CHEMICAL EMERGENCY, spill, leak, fire, exposure, or accident call
CHEMTREC 800-424-9300

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611

NET CONTENTS:

EPA Reg. No. 70506-18
EPA Est. No. 41876-1V-1

Storage and Disposal

Do not contaminate water, food, or food by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal. In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spill.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or residue is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

CONDITIONS OF SALE

AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract label security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

03/22/2003

8/24/03



ChemReg
INTERNATIONAL, LLC

G. LaRocca
10-16-03

1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
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WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Mr. George LaRocca (PM 13)

Re: Final Printed Labeling
Bifenthrin Technical Insecticide/Miticide, EPA Reg. No. 70506-18

Dear George:

On behalf of our client, United Phosphorus, Inc., enclosed please find 3 copies of the final printed labeling for the above product, per the notice of registration dated August 25, 2003. Please let me know if you have any questions.

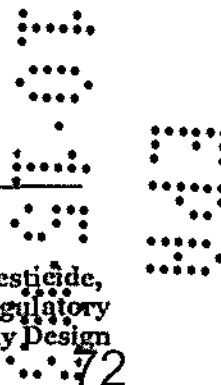
Regards,

Elizabeth Anne Brown

cc: United Phosphorus, Inc.

CONSULTANTS TO SUCCESSSM

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.





United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide -- Section I

1. Company/Product Number 70506-18	2. EPA Product Manager George LaRocca	3. Proposed Classification
4. Company/Product (Name) Bifenthrin Technical Insecticide/Miticide	PM # 13	<input type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/>	Amendment – Explain below	<input type="checkbox"/>	Final printed labels in response to
<input type="checkbox"/>	Resubmission in response to Agency letter dated	<input type="checkbox"/>	Agency letter dated
<input type="checkbox"/>		<input type="checkbox"/>	"Me Too" Application
<input checked="" type="checkbox"/>	Notification – Explain below	<input type="checkbox"/>	Other – Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Notification of Other Labeling Revisions per PB Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will be Packaged In:									
Child-Resistant Packaging		Unit Packaging		Water Soluble Packaging				2. Type of Container	
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____			
3. Location of Net Contents Information			4. Size(s) Retail Container			5. Location of label directions			
<input type="checkbox"/> Label	<input type="checkbox"/> Container					<input type="checkbox"/> On Label	<input type="checkbox"/> On Label accompanying product		
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stencilled <input type="checkbox"/> Other _____						

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Elizabeth Anne Brown	Title ChemReg International, LLC Authorized agent	Telephone No. (Include Area Code) 703-492-7905

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Elizabeth Anne Brown</i>	3. Title ChemReg International, LLC Authorized Agent
4. Typed Name Elizabeth Anne Brown	5. Date September 5, 2003

6 Date Application Received

(Stamped)

LSI

Bifenthrin Technical Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)

-2,2-dimethylcyclopropanecarboxylate* 99.4%

OTHER INGREDIENTS 0.6%

TOTAL 100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

KEEP OUT OF REACH OF CHILDREN WARNING

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611

EPA Reg. No. 70506-18
EPA Est. No.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL THE NATIONAL PESTICIDE
INFORMATION CENTER 1-800-858-7378

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning

May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer

systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This material requires further mixing before use

Only for formulation into an insecticide/miticide for

Terrestrial Non-Food:

Termiticide and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Ornamental plants, trees, shrubs, and vines (woody)

Residential Lawns

Indoor Insect Control

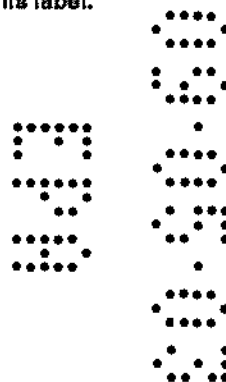
Non-Food/Feed Areas: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where foods may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (canning, bottling, wrapping, boxing), preparing, edible wastes, storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered a food area.

(2) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.



Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills.

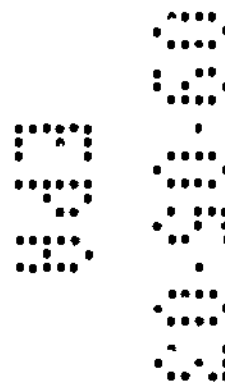
PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300

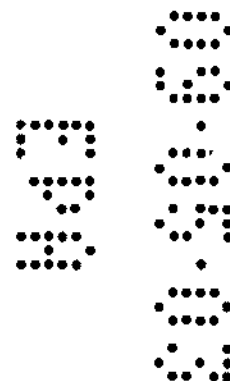


CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

EPA Approved. 08/25/2003
Revision (notification): 09/05/2003





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20004

EPA Reg. Number:

70506-18

Date of Issuance:

AUG 25 2003

Term of Issuance: Conditional

Name of Pesticide Product:

Bifenthrin Technical
Insecticide/Miticide

NOTICE OF PESTICIDE:

☒ Registration

(under FIFRA, as amended) ☐ Reregistration

Name and Address of Registrant (include ZIP Code):

United Phosphorus, Inc.
423 Riverview Plaza
Trenton, NJ 08611

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A), subject to the following provisions:

1. You must submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. You have applied for the registration of a product containing the active ingredient bifenthrin. The Agency has recently conditioned the original registration of which you are a follow-on with a new data requirement. A copy of EPA's letter, dated May 7, 2003, notifying FMC Corporation of the new data requirement is enclosed. As stated in paragraph 1, this registration will also be conditioned with that data requirement. Accordingly, you must take steps to ensure that these required data are submitted. The steps could include generating and submitting the data yourself, or you may offer to share with other registrants the cost of conducting testing.

The data requirement being imposed on this registration is as follows:

Signature of Approving Official:

Susan L. Stanton, for George T. LaRocca

Date:

AUG 25 2003

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 25 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
70506-18

Bifenthrin Technical Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)

-2,2-dimethylcyclopropanecarboxylate..... 99.4%

OTHER INGREDIENTS 0.6%

TOTAL 100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

KEEP OUT OF REACH OF CHILDREN WARNING

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611

EPA Reg. No. 70506-
EPA Est. No.

FIRST AID

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If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin or clothing

- Take off contaminated clothing.
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FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL
CHEMTREC 1-800-424-9300

PRECAUTIONARY STATEMENTS

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systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flames.

DIRECTIONS FOR USE

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Ornamental plants, trees, shrubs, and vines (woody)

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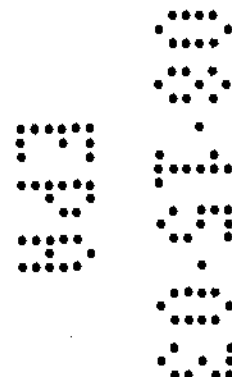
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Storage and Disposal

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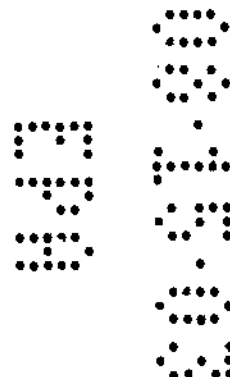
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FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300



CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE:

Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

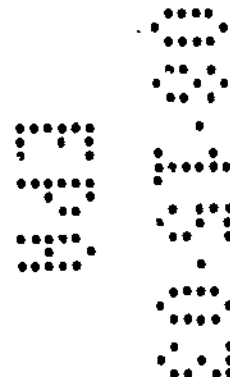
The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of United Phosphorus or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold United Phosphorus and Seller harmless for any claims relating to such factors.

United Phosphorus warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or United Phosphorus, and Buyer and User assume the risk of any such use. UNITED PHOSPHORUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall United Phosphorus or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF UNITED PHOSPHORUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE, AT THE ELECTION OF UNITED PHOSPHORUS OR SELLER, THE REPLACEMENT OF THE PRODUCT, OR COMPENSATION LIMITED TO DAMAGES NOT EXCEEDING THE FARE MARKET PURCHASE PRICE, AND SHALL NOT INCLUDE INCIDENTAL OR CONSEQUENTIAL DAMAGES.

United Phosphorus and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by the duly authorized representative of United Phosphorus.

Pending, not EPA Approved. 08/15/2003



Presubmission SS
ChemReg
INTERNATIONAL, LLC

G. LaRocca
8/19/03

1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

August 15, 2003

Document Processing Desk
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: George LaRocca (PM 13)

Re: Bifenthrin Technical Insecticide/Miticide (EPA File Symbol 70506-RI)
Response to Agency letter of August 6, 2003

Dear George:

On behalf of our client, United Phosphorus, Inc., this letter is in response to the Agency letter of August 6, 2003, regarding the above application for registration.

As a condition of registration, United Phosphorus, Inc. (UPI) agrees to provide the additional data required to support registration, as identified in your letter (data requirement OPPTS 870.6300, developmental neurotoxicity study). UPI will offer to cost share with other registrants. Please provide me with a copy of the data call-in sent to the other registrants or other documentation of the Agency requirement to other registrants. *(Note: Colvin Furlow reviewed EPA letter 5/7/03 and determined it could be released to other registrants)*

Attached please find data matrix forms (EPA Form 8570-35), revised to identify data supporting Guideline 84-4 (other genotoxic effects), as required in the Agency letter. Also enclosed is a revised Certification with Respect to Citation of Data (EPA Form 8570-34); offers have been sent to other registrants to address the additional data requirement. The data matrix also has been revised to reflect the MRIDs of the studies submitted by UPI in support of this application.

CONSULTANTS TO SUCCESSSM

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

ChemReg

INTERNATIONAL, LLC

Letter to G. LaRocca, August 15, 2003, page 2

Also enclosed are five copies of the draft label, revised as required in the Agency letter, along with one highlighted copy to identify the changes. Final printed labeling will be submitted once the Agency has registered this product and prior to release of any product for shipment.

Thank you for your attention to this matter. Please contact me immediately if there are any questions or if anything further is needed.

Regards,

Elizabeth Anne Brown

Elizabeth Anne Brown

cc: United Phosphorus, Inc.

84



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70506-RI	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bifenthrin Technical Insecticide/Miticide	PM # 13	
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated Aug. 6, 2003	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted		It "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		It "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Elizabeth Anne Brown	Title ChemReg International, LLC Authorized agent	Telephone No. (Include Area Code) 703-492-7905
------------------------------	---	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

2. Signature <i>Elizabeth Anne Brown</i>	3. Title ChemReg International, LLC Authorized Agent
4. Typed Name Elizabeth Anne Brown	5. Date August 15, 2003

6. Date Application Received

(Stamped)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

United Phosphorus, Inc.
 423 Riverview Plaza
 Trenton, NJ 08611
 609-392-8200

EPA Registration Number/File Symbol
 70506-RI

Active Ingredient(s) and/or representative test compound(s)
 bifenthrin

Date
 August 14, 2003

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Terrestrial Non-Food, Domestic Outdoor, Indoor

Product Name
 Bifenthrin Technical Insecticide/Miticide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature

Ann M. Tillman

Date

August 14, 2003

Typed or Printed Name and Title

Ann M. Tillman
 Technical Director



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: August 14, 2003	EPA Reg No./ File Symbol 70506-18	Page 1 of 4
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1 (830.1550)	Chemical identity	45654401	United Phosphorus Inc (UPI)	Own	
61-2a (830.1620)	Starting materials and manufacturing process	45654401	UPI	Own	
61-2b (830.1670)	Formation of impurities	45654401	UPI	Own	
62-1 (830.1700)	Preliminary analysis	45654401	UPI	Own	
62-2 (830.1750)	Certification of limits	45654401	UPI	Own	
62-3 (830.1800)	Analytical method	45654401	UPI	Own	
63-2 (830.6302)	Color	45654402	UPI	Own	
63-3 (830.6303)	Physical state	45654402	UPI	Own	
63-4 (830.6304)	Odor	45654402	UPI	Own	
None (830.7050)	UV/Visible Absorption	CITE ALL	FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
63-5 (830.7220)	Melting point	45838001	UPI	own	
63-7 (830.7300)	Density	45838001, 46008501, 46008502	UPI	own	
63-8 (830.7840)	Solubility	CITE ALL	FMC, Scotts, Andersons	pay	
63-9 (830.7950)	Vapor pressure	CITE ALL	FMC, Scotts, Andersons	Pay	
63-10 (830.7370)	Dissociation constant	CITE ALL	FMC, Scotts, Andersons	Pay	
63-11 (830.7550)	Octanol/water partition	CITE ALL	FMC, Scotts, Andersons	Pay	
63-12 (830.7000)	pH	45838001	UPI	own	
63-13 (830.6313)	Stability	45654403	UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/reduction	45838001	UPI	Own	
830.6315	Flammability	45838001	UPI	Own	
830.6316	explosibility	45838001	UPI	Own	
830.7220	Boiling point	45838001	UPI	Own	
830.7370	Dissociation constant	45838001	UPI	own	
71-1b (850.2100)	Avian acute oral toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-2 (850.2200)	Avian dietary toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-4 (850.2300)	Avian reproduction	CITE ALL	FMC, Scotts, Andersons	Pay	
72-1 (850.1075)	Fish acute toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-2 (850.1010)	Invertebrate toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-3 (850.1025 - 1055)	Estuarine/marine toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1300)	Invertebrate Chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1350)	Invertebrate chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-5 (850.1400)	Fish life early life cycle	CITE ALL	FMC, Scotts, Andersons	Pay	
141-1 (850.3020)	Honeybee acute contact toxicity	CITE ALL	FMC, Scotts, Andersons	pay	
81-1 (870.1100)	Acute oral- rat	45654404	UPI	Own	
81-2 (870.1200)	Acute dermal- rabbit/rat	45645505	UPI	Own	
81-3 (870.1300)	Acute inhalation - rat	00155286	FMC	Old	
81-4 (870.2400)	Primary eye irritation - rabbit	00132522	FMC	Old	
81-5 (870.2500)	Primary dermal irritation - rabbit	00132521	FMC	Old	
81-6 (870.2600)	Dermal sensitization	00132523	FMC	Old	
81-8 (870.6200)	Acute neurotoxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
82-1 (870.3100)	90-Day feeding	CITE ALL	FMC, Scotts, Andersons	pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product: Bifenthrin Technical Insecticide/Miticide
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-2 (870.3200)	21-Day dermal toxicity -- rats	CITE ALL	FMC, Scotts, Andersons	Pay	
82-7 (none)	Subchronic neurotoxicity - rat	CITE ALL	FMC, Scotts, Andersons	pay	
83-1a (870.4100)	Chronic feeding toxicity -- rodent	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-1b (870.4100)	Chronic feeding toxicity -- dog	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2a (870.4200)	Oncogenicity -- rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2b (870.4200)	Oncogenicity -- mouse	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3a (870.3700)	Teratogenicity -- rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3b (870.3700)	Teratogenicity -- rabbit	CITE-ALL	FMC, Scotts, Andersons	Pay	
✓ OPPTS 870.6300	Developmental Neurotoxicity	Data gap			
84-2	Mutagenicity studies	CITE-ALL	FMC, Scotts, Andersons	Pay	
✓ 84-4	Other genotoxic effects	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-1 (870.7485)	General metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-2	Dermal absorption	CITE-ALL	FMC, Scotts, Andersons	Pay	
161-1	Hydrolysis	CITE ALL	FMC, Scotts, Andersons	Pay	
161-2	Photodegradation in water	CITE ALL	FMC, Scotts, Andersons	Pay	
162-1	Aerobic soil metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
163-1	Adsorption/desorption	CITE ALL	MC, Scotts, Andersons	Pay	
164-1 (875.2200)	Field soil dissipation	CITE-ALL	FMC, Scotts, Andersons	Pay	
165-4	Bioaccumulation in fish	CITE-ALL	FMC, Scotts, Andersons	pay	
Special studies	Other	CITE ALL	Pyrethroid Working Group	pay	
132-1 (857.2100)	Foliar residue dissipation	CITE ALL	FMC, Scotts, Andersons	Pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

8/14/2003



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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
133-3 (875.2400, 2500)	Dermal exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
133-4 (857.2500)	Inhalation exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
201-1, 202-1 (840.1100, 835.4200)	Spray drift and droplet size	CITE ALL	UPI is a member of the Spray Drift Task Force	Own	

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Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			United Phosphorus Inc (UPI)	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
			UPI	own	
			UPI	own	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			UPI	own	
			UPI	own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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70506-18

Page 2 of 4

Applicant's/Registrant's Name and Address:

United Phosphorus, Inc.

423 Riverview Plaza

Trenton, NJ 08611

Product: Bifenthrin Technical Insecticide/Miticide

Ingredient: Bifenthrin (PC 128825)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
92			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	Own	
			UPI	own	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			UPI	Own	
			UPI	Own	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

8/14/2003



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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			MC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			Pyrethroid Working Group	pay	
			FMC, Scotts, Andersons	Pay	

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Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Spray Drift Task Force	Own	

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Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 8/14/2003
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 6 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI
Your Resubmission Dated June 11, 2003

The product referred to above will be acceptable for registration under FIFRA sec. 3(c)(7) provided that you:

1. Agree in writing to provide additional data as described below within the specified time frame:

You have applied for the registration of a product containing the active ingredient bifenthrin. The Agency has recently conditioned the original registration of which you are a follow-on with a new data requirement. This registration will also be conditioned with that data requirement. Accordingly, you must take steps to ensure that these required data are submitted. The steps could include generating and submitting the data yourself, or you may offer to share with other registrants the cost of conducting testing.

The data requirement which will be imposed on this registration is as follows:

Title of Study	Guideline Reference No.	Study Due Date
Developmental Neurotoxicity Study	870.6300	May 1, 2005

2. Submit or cite data to satisfy Guideline 84-4 (Other Genotoxic Effects). These data are required for products, such as yours, with terrestrial nonfood, domestic outdoor and indoor use patterns. With the exception of this guideline requirement, the data you have submitted/cited and listed on the data matrix, dated 4/11/2002, are adequate to support the proposed uses.

3. Correct the following minor typographical errors noted in the "Food/Feed Areas" paragraph on page 2 of the product label:

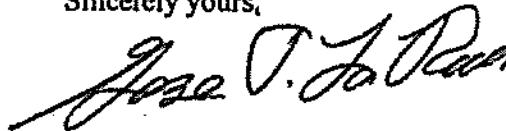
- Change "area" to "areas" near the end of the third line.
- Change "example" to "examples" near the end of the sixth line.
- In the second to last line, insert a period (".") after "(mills, dairies, edible oils, syrups)" and capitalize the next word ("Serving") to indicate the start of a new sentence.

EPA Reg. No. "70506-18" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when three (3) copies of the acceptable finished (printed) labels are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

Please respond within thirty (30) days from the date of this letter stating your intentions to comply with the information/label requests cited above. If no resubmission is received during this period, the application will be administratively withdrawn.

This letter does not constitute registration, and the product may not be lawfully marketed until it is registered. To expedite handling, please return a copy of this letter with your finished labeling. If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,



George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

70506-2I Bifenthrin Technical

1. Data Compensation - Selective method w/cite all option.
Matrix acceptable, except:

- * - must submit/cite data to FulFill guideline 84-4
(Other genotoxic effects)

2. Product Chemistry - Acceptable, per TRB reviews
of 5/21/03 and 7/31/03. CSF OK.
Determined to be substantially similar to
FMC's technical (279-3055)

3. Acute Tox: Submitted oral & dermal tox studies.
Cited remaining acutes - Acceptable per 1/8/03
review.

Oral	II
Dermal	III
Inhalation	III
Eye irritation	III
Skin irritation	IV
Derm. Sens.	Neg.

4. Label - minor typos on page 2.

Label - Acceptable w/minor corrections
on p. 2.

Bifenthrin Technical Insecticide/Miticide

FOR FORMULATION USE ONLY

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)
-2,2-dimethylcyclopropanecarboxylate*

99.4%

OTHER INGREDIENTS

0.6%

TOTAL

100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

**KEEP OUT OF REACH OF CHILDREN
WARNING**

United Phosphorus Inc.
423 Riverview Plaza
Trenton, NJ 08611

EPA Reg. No. 70506-
EPA Est. No.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed	<ul style="list-style-type: none">Call a poison control center or doctor immediately for treatment advice.Have person sip a glass of water if able to swallow.Do not induce vomiting unless told to do so by a poison control center or doctor.Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">Move person to fresh air.If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none">Take off contaminated clothing.Rinse skin immediately with plenty of water for 15-20 minutes.Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.Call a poison control center or doctor for treatment advice.

**FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE, CALL
CHEMTREC 1-800-424-9300**

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

Warning

May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer.

systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This material requires further mixing before use.

Only for formulation into an insecticide/miticide for

Terrestrial Non-Food:

Termiticide and Soil Contact Nonfumigation Treatment

Wood Treatment and Protection

Outdoor Insect Control

Ornamental plants, trees, shrubs, and vines (woody)

Residential Lawns

Indoor Insect Control

Non-Food/Feed Area: May be used to manufacture end-use products for use as a spot or crack and crevice treatment in non-food areas. Similar areas where insects hide or through which insects may enter can be treated. Examples of non-food areas include: garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling).

Food/Feed Areas: May not be used to manufacture products for use in food/feed areas. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food are served such as dining rooms but excluding areas where foods may be prepared or held. In the home all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Examples of food areas are areas for receiving, storage/packing (canning, bottling, wrapping, boxing), preparing, edible wastes, storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered a food area.

(2) Uses for which U.S. EPA has accepted the required data and/or citation of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with U.S. EPA requirements.

Formulators using this product are responsible for obtaining U.S. EPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal. ✓

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills. ✓

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation to Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. ✓

CONTAINER DISPOSAL

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration, if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner. ✓

FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident, call
CHEMTREC 1-800-424-9300 ✓

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE:

Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of United Phosphorus or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold United Phosphorus and Seller harmless for any claims relating to such factors.

United Phosphorus warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or United Phosphorus, and Buyer and User assume the risk of any such use. UNITED PHOSPHORUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall United Phosphorus or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF UNITED PHOSPHORUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE, AT THE ELECTION OF UNITED PHOSPHORUS OR SELLER, THE REPLACEMENT OF THE PRODUCT, OR COMPENSATION LIMITED TO DAMAGES NOT EXCEEDING THE FARE MARKET PURCHASE PRICE, AND SHALL NOT INCLUDE INCIDENTAL OR CONSEQUENTIAL DAMAGES.

United Phosphorus and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by the duly authorized representative of United Phosphorus.

Pending, not EPA Approved. 03/20/2002

DATE OUT: July 31, 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Bifenthrin Technical
Insecticide/Miticide

DP BARCODE No.: 291574
REG./File Symbol No.: 70506-RI
DECISION: 219958

FROM: Linda L. Kutney, Chemist *Linda L. Kutney*
Product Chemistry Team
Technical Review Branch/RD (7505C) *7/31/03*

S/BW 7/31/03

TO: Marion Johnson, Susan Stanton PM-3
Insecticide Branch/ RD (7505C)

PC CODE: 128825

USE: Insecticide Technical Product with No associated Food
Uses

INTRODUCTION:

United Phosphorus, Inc., has submitted product chemistry data to support their claim that their product, Bifenthrin Technical Insecticide/Miticide, is similar to FMC's Bifenthrin technical, Reg. No. 279-3055. Data were submitted under MRID 46008501 and 46008502.

SUMMARY OF FINDINGS:

TRB has denied the claim of similarity between the above-mentioned products in previous reviews, due to differences in their reported physical chemical properties, i.e., density and described physical state (12/11/02 and 5/21/03 reviews).

TRB CONCLUSIONS:

According to published literature (Pesticide Manual-11th Ed., 1997), the physical state of bifenthrin varies from a viscous liquid, crystalline or waxy solid, having a Specific Gravity/density of 1.210. According to the Registrant, as bifenthrin is purified, it becomes more crystalline and less dense, the Registrant reports that it is solid above 97.5% and liquid or waxy semi-solid below that purity.

The proposed product has a nominal concentration (NC, 1/9/03 CSF) of 98.2 with certified limits for the cis isomer of 95.1 - 100.0, with a density of 0.4593 g/ml = 3.8 lb/gal.

The cited product (3/22/01 CSF) had a NC of 91.1%, with certified limits for the cis isomer of 86.3 - 96.0%, with a density of 1.26 g/ml = 10.5 lb/gal.

Because the purities of Bifenthrin varies for both the proposed product and cited product, density measurements and physical state descriptors are not good indicators of similarity. Because the proposed product contains no new impurities and has fewer total impurities, TRB reverses its previous conclusion and grants the similarity request.

Briefly, the results of the density tests submitted are:

MRID 46008501

99.26% Bifenthin Bulk Density

Pour 0.452 - 0.454, avg. 0.453 g/ml

Tap 0.0554 - 0.558, avg. 0.556 g/ml

This is an acceptable study

MRID 46008502

99.0% Bifenthin Density of Melted substance (melted completely at 70C)

1.2231, 1.2085, 1.2131 g/ml, avg. 1.2149 g/ml

This is not an acceptable study, it is not acceptable to melt the sample and then determine its density.

NOTE TO THE PM:

If time permits, could you contact FMC and ask if the density of their Bifenthrin technical, Reg. 279-3055 has changed since the 10.5 lb/gal value (1.26 g/ml) present in box 7 of their 3/22/01 CSF? This may be a very old value that should have been updated years ago.

(Notes Re: OP's selective Citation Matrix)

§158.240 Residue chemistry data requirements.

Required
Not Sure

Addressed
on Matrix

Not Addressed
on Matrix

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Chemical identity	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171-2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]			171-3
Nature of the residue:													
Plants	(12), (14)	[R]	[R]	[R]	[CR]	[CR]	PAIRA	PAIRA	171-4
Livestock	(3), (13), (14)	[CR]	[CR]	[CR]	[CR]	[CR]	PAIRA and plant metabolites.	PAIRA and plant metabolites.	171-4
Residue analytical method.	(4), (12), (14), (15)	[R]	[R]	[R]	[CR]	[CR]	TGAI and metabolites.	TGAI and metabolites.	171-4
Magnitude of the residue:													
Crop field trials	(12), (14)	[R]	[R]	[R]	[CR]	[CR]	TEP	TEP	171-4
Processed food/ feed.	(5), (14)	[CR]	[CR]	[CR]	[CR]	EP	EP	171-4
Meat/milk/poultry/ eggs.	(8), (14)	[CR]	[CR]	[CR]	[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171-4
Potable water	(7)	[R]	[R]	EP	EP	171-4
Fish	(6)	[R]	[R]	EP	EP	171-4
Irrigated crops	(9)	[CR]	[CR]	EP	EP	171-4
Food handling	(10), (14)	[CR]	EP	EP	171-4
Reduction of residue	(11), (14)	[CR]	[CR]	[CR]	[CR]	Residue of concern.	Residue of concern.	171-6
Proposed tolerance	(12), (14)	[R]	[R]	[R]	[CR]	Residue of concern.	Residue of concern.	171-6
Reasonable grounds in support of the petition.	(14)	[R]	[R]	[R]	[CR]	171-7
Submittal of analytical reference standards.	(14)	[R]	[R]	[R]	[CR]	PAIRA	PAIRA	171-13

Key: R=Required data; CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; EP=End-use product; TEP=Typical and use product; MP=Manufacturing-use product; J=Grain; S.S.=[R], [CR], [R] indicate data requirements that apply when an experimental use permit is being sought.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The same chemical identity data as required under subpart C of this part are required, with emphasis on impurities that could constitute a residue problem.

(2) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(4) A residue method for enforcement of tolerances is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(5) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.

- (3) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.
- (7) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purposes, by man or animals.
- (8) Data on residues in fish are required whenever a pesticide is to be applied directly to water inhabited by fish.
- (9) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
- (10) Data on residues in foodstuffs in food handling establishments are required whenever a pesticide is to be used in foodstuffs handling establishments. Establishments and facilities used in food or food handling establishments are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.
- (11) Fluctuation of residue data are required when the assumption of tolerance level residues would result in predicted exposure of an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in cases new data are revealed which indicate the pesticide is more toxic than initially determined.
- (12) The proposed tolerance must reflect the maximum residue likely to occur in crops and multi-use/poultry eggs.
- (13) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerance was established.
- (14) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.
- (15) For all food uses, data on whether the FDA/USDA maximum residue methodology would detect and identify the pesticide are required.

(49 FR 42851, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 53 FR 34203, June 23, 1988)

§ 158.290 Environmental fate data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the environmental fate data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidance reference No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP		
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood							
Degradation studies-lab														
Hydrolysis		PR	PR	PR	PR	PR	PR	PR	PR		TGAJ or PAJRA	TGAJ or PAJRA	151-	
Photodegradation:														
In water		R	R	R	R			R			TGAJ or PAJRA	TGAJ or PAJRA	151-	
On soil	(1)	CR						CR			TGAJ or PAJRA	TGAJ or PAJRA	151-	
In air	(2)	CR									TGAJ or PAJRA	TGAJ or PAJRA	151-	
Metabolism studies-lab														
Aerobic soil		PR	PR			R	R	PR	R		TGAJ or PAJRA	TGAJ or PAJRA	152-	
Anaerobic aquatic				R	R			R			TGAJ or PAJRA	TGAJ or PAJRA	152-	
Aerobic aquatic				PR	PR						TGAJ or PAJRA	TGAJ or PAJRA	153-	

Metals studies													
Leaching and adsorption/ desorption		PR	PR	R	R	R	R	PR	R		TGAJ or PAJRA	TGAJ or PAJRA	153-1
Volatility:													
(Lab)	(2)	CR				CR	CR				TEP	TEP	153-2
(Field)	(2)	CR				CR	CR				TEP	TEP	153-3
Dispersion studies-field													
Soil		R	R						R		TEP	TEP	154-1
Aquatic (sediment)				R	R						TEP	TEP	154-2
Forestry								R			TEP	TEP	154-3
Corrosion and tank release	(2)										TEP	TEP	154-4
Soil, long-term	(4)	CR		CR							TEP	TEP	154-5
Accumulation studies													
Rotational crops:													
(Continued)	(3)	CR		CR							PAJRA	PAJRA	155-1
(Field)	(3)	CR		CR							TEP	TEP	155-2
Irrigated crops	(7)			CR							TGAJ or PAJRA	TGAJ or PAJRA	155-3
In fish	(8)	CR		CR				CR			TEP	TEP	155-4
In aquatic non-target organisms.	(5), (6)			CR							TEP	TEP	155-5

Key: R=Required; CR=Conditionally required; ()=brackets (e.g., PR, CR). Indicate data requirements that apply when an experimental use permit is being sought; TGAJ=Technical grade of the active ingredient; PAJRA="Pure" active ingredient-radio labeled; TEP=typical end use product; EP=End use product.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

AAA(2) Required on case by case basis depending on product use pattern and other pertinent factors.

AAA(3) Not required if anaerobic aquatic metabolism study has been conducted.

AAA(4) Required if pesticide residues do not readily desorb in soil.

AAA(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

AAA(6) Field accumulation study is required if significant pesticide residues are likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

AAA(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

AAA(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

AAA(9) Required unless tolerance or action level for fish has been granted.

(49 FR 42851, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988)

§ 158.340 Toxicology data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Odds-free reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Acute testing											MP and TGAJ	EP or EP duration and TGAJ	11-1
Acute oral toxicity—rat	(1)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGAJ	EP or EP duration and TGAJ	11-2
Acute dermal toxicity	(1), (2)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGAJ	EP or EP duration and TGAJ	11-3
Acute inhalation toxicity—rat	(14)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP and TGAJ	EP or EP duration and TGAJ	11-4
Primary eye irritation—rabbit	(2)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP	EP	11-5
Primary dermal irritation	(1), (2)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP	EP	11-6
Dermal sensitization	(2), (19)	PI	PI	PI	PI	PI	PI	PI	PI	PI	TGAJ	TGAJ	11-7
Acute delayed neurotoxicity—hen	(19)	PI	PI	PI	PI	PI	PI	PI	PI	PI	MP	EP	11-8
Subchronic testing											TGAJ	TGAJ	11-9
90-day feeding studies—rodent and nonrodent	(17)	PI	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ and EP	11-10
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ	11-11
90-day dermal	(3), (18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ	11-12
90-day inhalation—rat	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ	11-13
90-day neurotoxicity: Man	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ	11-14
Man	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAJ	TGAJ	11-15
Chronic testing											TGAJ	TGAJ	11-16
Chronic feeding—2 spp. rodent and nonrodent	(2), (13), (20)	PI	CR	PI	CR	PI	CR	PI	CR	CR	TGAJ	TGAJ	11-17
Oncogenicity study—2 spp. rat and mouse preferred	(2), (21)	R	CR	R	CR	R	CR	R	CR	CR	TGAJ	TGAJ	11-18
Toxicogenicity—2 species	(10), (13)	PI	CR	PI	CR	PI	CR	PI	CR	CR	TGAJ	TGAJ	11-19
Reproduction, 2-generation	(13), (14)	PI	CR	PI	CR	PI	CR	PI	CR	CR	TGAJ	TGAJ	11-20
Mutagenicity testing											TGAJ	TGAJ	11-21
Gene mutation	(22)	PI	R	PI	R	PI	R	R	R	R	TGAJ	TGAJ	11-22
Structural chromosomal aberration	(22)	PI	R	PI	R	PI	R	R	R	R	TGAJ	TGAJ	11-23
Other genotoxic effects	(22)	PI	R	PI	R	PI	R	R	R	R	TGAJ	TGAJ	11-24

Special testing													
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	PAI or PAI/A	PAI or PAI/A	11-25
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choles	Choles	11-26
Domestic animal safety	(12)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choles	Choles	11-27

AAKey: R=Required data; CR=Conditionally required; I=Indicates (a) PI, (CR) indicates data requirements that apply when an experimental use permit is being sought; MP=Manufacturing-use product; EP=End-Use Product; (a) indicates that these data requirements that include applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source; TGAJ=Technical grade of the active ingredient; PAI=Pure active ingredient; PAI/A=Pure active ingredient, radio-labeled; Choles=Choice of several test substances, depending on studies required.

(1) The following notes are related to column two of the table contained in paragraph (a) of this section.

(2) Not required if test material is a gas or highly volatile.

(3) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as irritant category I on the basis of potential eye and dermal irritation effects.

(4) Required unless repeated dermal exposure does not occur under conditions of use.

(5) Not required unless test material is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.

(6) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.

(7) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.

(8) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity of a closely related structural to a compound which can induce these effects.

(9) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.

(10) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.

(11) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:

(12) Chronic rodent feeding study (food use pesticides)—24 months.

(13) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.

(14) Chronic nonrodent (i.e., dog) feeding study—12 months.

(15) Mouse oncogenicity study—18 months.

(16) Rat oncogenicity study—24 months.

(17) Required to support products intended for food uses and to support products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.

(18) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(19) Required on a case by case basis.

(20) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic lead study is required to support a temporary tolerance.

(21) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a first generation (or longer) interim report on a reproduction/reproduction study is required to support a temporary tolerance.

(22) A toxicology study in one species is required to support a temporary tolerance.

(23) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).

(24) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(a) Human exposure is via the oral route.

(b) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).

(c) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via skin contact.

(ii) Expected human skin contact is not purposeful, and such exposure is of limited frequency and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).

(d) Data from a subchronic 90-day dermal toxicity study are not required.

(15) Required if pesticide use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:

(i) Data from a subchronic oral study are not required.

(ii) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

(20) Required if either of the following criteria are met:

(i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).

FAC submitted derm. penetration studies (was used in exp. assessment, since derm. endpoint selected)

100

101

- (1) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.
- (2) Required if any of the following criteria are met:
- (A) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
 - (i) Is structurally related to a recognized carcinogen.
 - (ii) Is a substance that causes mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.
 - (iii) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.
- (3) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
- (4) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the frequency of exposure or the duration of exposure (for example, pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
- (5) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in § 158.302:
- (i) Gene mutations.
 - (ii) Structural chromosomal aberrations.
 - (iii) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair, mammalian cells transformation, target organ cell analysis.
- (6) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.
- (7) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed ball houses).
- (8) Required if chronic feeding or oropharyngeal studies are required.
- (9) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15093, 15099, May 4, 1988; 56 FR 34203, June 23, 1993]

§ 158.390 Reentry protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Foliar disposition	(1)	CR	CR	CR	CR			CR			TEP	TEP	158-1
Soil disposition	(1), (4)	CR	CR	CR	CR			CR			TEP	TEP	158-1
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR			CR			TEP	TEP	158-2
Inhalation exposure	(1), (2), (3)	CR	CR	CR	CR			CR			TEP	TEP	158-4

Key: CR=Conditionally required; TEP=Typical end-use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

- (1) Data are required if the following conditions are met:
- (A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
 - (B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m³ (for a one-hour exposure); or
 - (C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
 - (D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
 - (E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
- (2) And if end-use product is to be registered for:
- (A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.

(3) Application to outdoor tree nursery and forestry operations.

(4) Application to turf crops and commercial applications to turf.

(5) Application to parks and arboreta; or (6) application to aquatic crops.

(7) And if human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.

(8) Data required if appropriate surrogate data are not available.

(9) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.

(10) Soil disposition data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15093, May 4, 1988, and amended at 56 FR 34203, June 23, 1993]

§ 158.440 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP		
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood							
Droplet size spectrum	(1)	CR	CR	CR	CR	CR	CR	CR			TEP	TEP	158-1	
Drift field evaluation	(1)	CR	CR	CR	CR	CR	CR	CR			TEP	TEP		

Key: CR=Conditionally required; TEP=Typical end use product.
(b) NOTES.— The following are relevant to the use of the data in this table:

Key: CR=Conditionally required; TEP=Typical end-use product.

(b) NOTES.—The following are referenced in column two of the table contained in paragraph (a) of this section.

- (1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submission of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
- (2) [Reserved]

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15093, May 4, 1988, and amended at 56 FR 34203, June 23, 1993]

§ 158.490 Wildlife and aquatic organisms data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian and mammalian testing													
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1) [R]	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAJ	TGAJ	71-1

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Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MEP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	PR	PR	PR	PR	CR	CR	PR	PR	CR	TGAJ	TGAJ	71-3
Wild mammal toxicity	(2)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-3
	(3)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR			CR	CR		TEP	TEP	71-3
Simulated and actual field testing—mammals and birds.													
Aquatic organism testing													
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	PR	PR	PR	PR	CR	CR	PR	PR	CR	TGAJ	TGAJ	71-3
Acute LC ₅₀ freshwater invertebrates (preferably Daphnia).	(1), (7)	PR	PR	PR	PR	CR	CR	PR	PR	CR	TGAJ	TGAJ	71-3
Acute LC ₅₀ estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-3
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-3
Fish—life cycle.	(6)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	71-3
Aquatic organism accumulation.	(8)	CR	CR	CR	CR			CR	CR		TGAJ, PAL, or degradation product.	TGAJ, PAL, or degradation product.	71-3
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR			CR	CR		TEP	TEP	71-3

Key: PR=Required; CR=Conditionally required; —=Indicates (a) PR, (CR) indicates data requirements that apply when an experimental use permit is being sought; TGAJ=Technical grade of the active ingredient; TEP=Typical end-use product; PAL=Thick active ingredient.

(b) Notes.—The following notes are submitted in column two of the table contained in paragraph (a) of this section.

(1) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD₅₀ (bobwhite), avian dietary LC₅₀ (bobwhite), freshwater fish LC₅₀ (rainbow trout) and acute LC₅₀ freshwater invertebrates (Daphnia).

(2) Liquid formulation indoor use products require all tests listed under (b)(1)(A) of this section except the avian oral LD₅₀.

(3) Data are not required to support:

(A) Indoor and-use products consisting of a gas-highly volatile liquid or a highly reactive solid.

(B) Indoor and-use products for which there is a manufacturing use product registration.

(4) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

(5) Data required if one or more of the following criteria are met:

Submitted by FMC, but UP's tech. only for non-food uses (no field crops). Per George - not required.

- (6) Fish may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
 - (7) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.
 - (8) The pesticide or any of its major metabolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
 - (9) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.
- NOTE:** Prior to conducting this test to support the registration of an article, the applicant should consult the Agency.
- (4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.
- (5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:
- (A) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
 - (B) If any LC₅₀ or EC₅₀ value determined in acute toxicity testing is less than 1 mg/L or
 - (C) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing.
 - (D) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist:
- (A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
 - (B) Physicochemical properties indicate cumulative effects.
 - (C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
 - (D) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:
- (A) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
 - (B) If studies of other organisms indicate the reproductive physiology of fish may be affected. **NOTE:** The applicant should consult the Agency prior to these tests to support the registration of a pesticide.
 - (7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:
- (A) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.
 - (B) The LC₅₀ or EC₅₀ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.
 - (C) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
 - (8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

[49 FR 42881, Oct. 24, 1994. Redesignated at 63 FR 15003, May 4, 1998, and amended at 56 FR 34209, June 23, 1993]

§ 158.540 Plant protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MEP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity - Non-target area phytotoxicity. Tier I	(1)										EP	EP	121
Seed germination/seedling emergence.	(2)	R		R				R			TGAJ	TGAJ	122
Vegetative vigor	(2)	R		R				R			TGAJ	TGAJ	122

N/A

Kind of data required	(b) Notes	General use patterns									Test substances		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Aquatic plant growth	(2)		R		R			R			TGAJ	TGAJ	122-2
Tier II: Seed germination/seedling emergence	(2)		CR		CR			CR			TGAJ	TGAJ	123-1
Vegetative vigor	(3)		CR		CR			CR			TGAJ	TGAJ	123-1
Aquatic plant growth	(4)		CR		CR			CR			TGAJ	TGAJ	123-2
Tier III: Terrestrial field	(5)		CR		CR			CR			TEP	TEP	124-1
Aquatic field	(4)		CR		CR			CR			TEP	TEP	124-2

Key: CR=Conditionally required; TGAJ=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Data are required for Special Review and certain public health situations.

(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation, the aquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:

(a) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.

(b) The product may pose hazards to endangered or threatened species.

(c) Special Review has been initiated on the product.

(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.

(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

(49 FR 42921, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 53 FR 34203, June 23, 1993)

§ 158.590 Nontarget insect data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use pattern									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect feeding—pollinators													
Honey bee acute oral LD ₅₀	(1)	CR	CR	CR	CR			CR	CR		TGAJ	TGAJ	141—
Honey bee—toxicity of residues on foliage	(1), (2)	CR	CR	CR	CR			CR	CR		TEP	TEP	141—
Honey bee subacute feeding study	(3)												141—
Field testing for pollinators	(4)	CR	CR	CR	CR			CR	CR		TEP	TEP	141—

Nontarget insect feeding—aquatic insects.	(5)												142-1
Acute toxicity to aquatic insects.	(5)												142-1
Aquatic insect life-cycle study.	(5)												142-3
Simulated or actual field testing for aquatic insects.	(5)												143-1
Nontarget insect feeding—predators and parasites.	(5)												143-3

Key: CR=Conditionally required; []=brackets (i.e., CR) indicate data requirements that apply to products for which an experimental use permit is being sought; TGAJ=Technical grade of the active ingredient; TEP=Typical end-use product.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required only if proposed use will result in honey bee exposure.

(2) Required only when formulation contains one or more active ingredients having an acute LD₅₀ of less than 1 microgram/bees.

(3) This requirement is reserved pending development of test methodology.

(4) May be required under the following conditions:

(a) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).

(b) Data from residual toxicity studies indicate extended residual toxicity.

(c) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.

(5) This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

(49 FR 42921, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 53 FR 34203, June 23, 1993)

§ 158.640 Product performance data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)									CR		EP	91-
Products requiring confirmatory data.	(1)									CR		EP	91-
Products for use on fabrics and linens.	(1)									CR		EP	91-
Air sanitizers	(1)									CR		EP	91-
Products for control of microbial pests associated with human and animal wastes.	(1)									CR		EP	91-

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Products for treating water systems.	(1)			[CR]						CR		EP	§1-6
Efficacy of fungicides and nematocides													
Products for control of organisms producing mycotoxins.	(1)	[CR]		[CR]		[CR]						EP	§3-10
Efficacy of Vertebrate Control Agents													
Aerial toxicants	(1)	(P)	(P)						(P)	(P)		EP	§5-5
Aerial repellents	(1)	(P)	(P)						(P)			EP	§5-6
Aerial brightening agents	(1)	(P)	(P)						(P)			EP	§5-7
Bait toxicants and repellents	(1)									(P)		EP	§5-9
Commercial rodenticides	(1)	(P)	(P)						(P)	(P)	TEP	EP	§5-10
Rodenticides on farm and rangelands.	(1)	(P)	(P)						(P)			EP	§5-12
Rodent fumigants	(1)	(P)	(P)						(P)	(P)		EP	§5-13
Rodent reproductive inhibitors	(1)	(P)	(P)						(P)	(P)		EP	§5-15
Mammalian pesticides	(1)	(P)	(P)						(P)			EP	§5-17

Key: P=Required; CR=Conditionally required; ()=Indicates (i.e., (P), (CR)) indicate data requirements that apply to products for which an experimental use permit is being sought. EP=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(2) Notes: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the immediate environment or a claim to control vertebrates (such as rodents, birds, bats, canines, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

(2) [Reserved]

[40 FR 42831, Oct. 24, 1984, as amended at 50 FR 46768, Nov. 13, 1985. Redesignated at 53 FR 15093, May 4, 1988, and amended at 58 FR 34230, June 23, 1993]

§ 158.600 Biochemical pesticides data requirements.

(a) Biochemical pesticide product analysis data requirements—(1) Table, Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—product analysis data requirements and the

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product identity		(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	MP	EP	151-10
Manufacturing process	(3)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	MP and TGAJ	EP and TGAJ	151-11
Discussion of formation of unintentional ingredients	(3)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	MP and TGAJ	EP and TGAJ	151-12
Analysis of samples	(3)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAJ	EP and TGAJ	151-13
Certification of limits		(P)	R	(P)	R	(P)	R	R	R	R	MP	EP	151-15
Analytical methods		(P)	R	(P)	R	(P)	R	R	R	R	MP and TGAJ	EP and TGAJ	151-16
Physical and chemical properties		(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	(P)	MP and TGAJ	EP and TGAJ	151-17
Submittal of samples	(3)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAJ, PAL	EP, TGAJ and PAL	151-18

Key: P=Required; CR=Conditionally required; MP=Manufacturing-use product; EP=End-use product; TGAJ=Total guideline analysis; PAL=Product analysis; R=Required, provided that the active ingredient(s) from which the product is derived is/are listed in the registration dossier.

Key: P=Required; CR=Conditionally required; MP=Manufacturing use product; EP=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAJ=Technical grade of the active ingredient; ()=Indicates (i.e., (P), (CR)) indicate data requirements that apply when an experimental use permit is being sought.

(2) Notes: The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.

(3) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production. If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(4) Required to support registration of each manufacturing use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

(5) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) Biochemical pesticides residue data requirements. (1) Table, Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—residue data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns										Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP		
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood							
Chemical identity _____	(3), (5), (6)(i)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAJ _____	TGAJ _____	153-3	
Directions for use _____	(3), (5), (6)(i)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	_____	_____	153-3	
Nature of the residue:														
Plants _____	(3), (6)(i)	[CR]	_____	[CR]	_____	[CR]	_____	_____	[CR]	_____	PAIRA _____	PAIRA _____	153-3	
Livestock _____	(3), (6)(i), (6)(v)	[CR]	_____	[CR]	_____	[CR]	_____	_____	[CR]	_____	PAIRA and plant _____	PAIRA and plant _____	153-3	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 16 2003

MEMORANDUM

SUBJECT: Request for Expedited Review

FROM: Marion Johnson, Chief
Insecticide Branch
Registration Division (7505C)

A handwritten signature in black ink, appearing to be "Marion Johnson", written over the typed name and title.

TO: Deborah McCall, Chief
Technical Review Branch
Registration Division (7505C)

The Insecticide Branch hereby requests an expedited review of additional product chemistry data submitted to support registration of Bifenthrin Technical Insecticide/Miticide (EPA File Symbol: 70506-RJ).. These data were forwarded to TRB/CHEM on July 8, 2003 under Data Package DP291574. IB requests that the review be completed within 2 weeks if possible. Thank you very much for your cooperation in this matter.

DATA PACKAGE BEAN SHEET

Date: 08-Jul-2003

Page 1 of 3

***** Registration Information *****

Registration: 70506-RI - BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE

Company: 70506 - UNITED PHOSPHORUS INC

Risk Manager: RM 03 - Marion - Johnson - (703) 305-6788 Room# CM-2 219

Risk Manager Reviewer: Susan Stanton - SSTANTON

Sent Date: 15-Apr-2002

Calculated Due Date: 08-Oct-2002

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: NEW REGISTRATION;OLD INGREDIENT;MINOR CHANGE;

Ingredients: 128825

***** Data Package Information *****Expedite: ☐ Yes ☒ No

Date Sent: 08-Jul-2003

Due Back:

DP Ingredient: 128825, Bifenthrin

DP Title: Additional Density Information

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #:

Assigned ToDate InDate Out

Organization: RD / TRB

Administrative Due Date: 05-Dec-2003

Team Name:

Negotiated Due Date:

Reviewer Name:

Projected Completion Date:

Factor Name:

***** Studies Sent for Review *****

Printed on Page 2

***** Additional Data Package for this Decision *****

Printed on Page 3

***** Data Package Instructions *****

ATTN: Shyam Mathur

In Linda Kulney's May 20, 2003 review, she determined that United Phosphorus's new bifenthrin technical was not substantially similar to FMC's registered bifenthrin technical, in part because of differences in density between the two products. I discussed this with you and you suggested that the company develop additional density data, perhaps using a different method. They have done so and submitted it along with an explanation of the density of bifenthrin in

relation to its purity and physical state. Please review the new data (MRID/s 460085-01 and 460085-02) and let us know whether the new information supports the determination that the product is substantially similar to FMC's technical.

Thanks,
Susan Stanton

DP#: (291574)

*** Additional Data Package for this Decision ***

Decision#: (219958)

DP #	Division/Branch	Data Sent	Date Due	Instructions?	CSF	label
285142	RD / TRB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
285142	RD / IB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
285143	RD / TRB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
285143	RD / IB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
288051	RD / TRB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No
288051	RD / IB	08-Jul-2003	08-Jul-2003	<input type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

George LaRocca
07/16/2003 03:37 PM

To: Elizabeth Brown <brown@chemreg.com>
cc: "Tillman Ann (E-mail)" <atillman@upi-usa.com>, Debbie
Edwards/DC/USEPA/US@EPA, Marion
Johnson/DC/USEPA/US@EPA, Susan Stanton/DC/USEPA/US@EPA
Subject: Re: request for urgent meeting re pending application EPA File Symbol
70508-RI

Elizabeth:

I don't believe a meeting is necessary at this time. Based upon the chronology of events associated with this application for registration and the one remaining issue about physical state and density I will request an expedited review(2 to 3 weeks) of the additional information you recently provided. If there are still questions associated with this issue at that time that cannot be easily resolved then I will schedule a meeting with you and UPI.

George LaRocca
Elizabeth Brown <brown@chemreg.com>



Elizabeth Brown
<brown@chemreg.com>
>
07/11/03 12:33 PM

To: George LaRocca/DC/USEPA/US@EPA
cc: Susan Stanton/DC/USEPA/US@EPA, Marion
Johnson/DC/USEPA/US@EPA, Debbie
Edwards/DC/USEPA/US@EPA, "Tillman Ann (E-mail)"
<atillman@upi-usa.com>
Subject: request for urgent meeting re pending application EPA File Symbol
70508-RI

George:

On behalf of our client, United Phosphorus Inc., I am requesting a meeting as quickly as possible to discuss and address current issues regarding the above application for registration of Bifenthrin Technical. We request the attendance of yourself, Susan Stanton, Marion Johnson, Debra Edwards, and the appropriate chemists. We request that a meeting be held any time the week of July 21. Dr. Ann Tillman (UPI) and I (representing UPI) will attend.

The reason for this request is that on July 8, 2003, Susan Stanton informed me that UPI's explanation to a verbal question raised by the chemist was being routed for full review, with a due date for response from Chemistry in December 2003. We feel that this is entirely unnecessary and is another unreasonable delay in the consideration of UPI's application. Given the question and UPI's response, we believe that the issue can and should be quickly resolved.

As you know, UPI filed an application for registration of Bifenthrin Technical on 4/8/02. On 4/25/02, the Agency sent a letter stating that the application was considered incomplete because EPA Form 8570-34 (Certification with Respect to Citation of Data) was not included. Following our letter to the Agency of 5/8/02 and the Agency's letter in response on 6/3/02, along with other meetings on the issue of the timing of filing of that form, the Agency in its letter of 8/14/02 confirmed that EPA Form 8570-34 is not required in order for the Agency to begin reviewing the application. However, to ensure no further issues, UPI submitted EPA Form 8570-1 on 8/29/02. **But the actions by the Agency resulted in a 4 month delay in starting review of UPI's application.**

On December 16, 2002, UPI received the Agency's Product Chemistry Review of the application (DP Barcode D285142, dated 12/11/02). In that review, the Agency determined that additional physical/chemical characteristics data needed to be provided. Other issues identified in that review were resolved by phone discussions with the Agency.

On January 15, 2003, UPI submitted all additionally required product chemistry data, with the exception of the 1-year storage stability study, requesting that submission of the final report be a condition of registration. We confirmed that the study was underway and committed to providing it. On 4/10/2003, I talked with Susan Stanton to determine whether the 0-day report should be submitted; she said it should not be submitted but to wait for the final report which would be a condition of registration. She also identified that Chemistry reviews were due back in early May.

UPI thus has fulfilled all product chemistry data requirements on its technical material with its own studies, with the exception of those data requirements where the PAI is the test material and long term stability (which would be a condition of registration). The Agency has confirmed the UPI can cite and offer to pay data compensation for those data requirements, which UPI has done.

On May 23, 2003, Susan Stanton called me to ask whether we could explain why UPI's technical (98.2% purity) was a solid (crystalline powder) while the FMC technical (previously 89%, now 94%) is a viscous liquid. I explained that the physical state changes with the purity.

On June 4, 2003, Susan Stanton again called, identifying that the chemist still is having trouble with the different densities of UPI's and FMC's technical materials. She asked that we provide an explanation and/or new study using a different method that showed the same density for the UPI material as for FMC's as quickly as possible, and said that the study did not need to be glp. She said that providing that information would allow the chemist to quickly complete his review.

On June 9, 2003, I called Susan Stanton to let her know that 1) the difference in density and physical state is due to well-known and well-documented association with purity of the material which we could provide in letter form, 2) that UPI had confirmatory data to document that the density value already submitted and reviewed is correct. She asked that both be submitted, with a full copy of the confirmatory reports given to her as well as submitted through front-end processing, just to speed the process. She indicated that there should be very little delay to review the explanation. The explanatory letter and confirmatory data were submitted and hand-delivered on June 11, 2003.

As indicated above, on July 8, 2003, Susan Stanton called to let me know that it will be another 5-6 months before the Agency can review a written explanation of a well-known and documented effect of purity on physical state and density. The confirmatory data do not change or replace the already reviewed study for density of UPI's Bifenthrin technical; those data only confirm the results and explain how changing the physical state of UPI's material can change the density, consistent with the explanation provided, in relation to FMC's product.

Those confirmatory data are not required to support registration and would not have been submitted without the Agency's assurance that there would not be a delay in review of the pending application. The explanation provided in letter form is adequate to address the chemist's questions and will not require a detailed review.

We believe that a delay of an additional 5-6 months, combined with the earlier 4 month delay, are unfair to United Phosphorus. We have very much appreciated the Agency's willingness to discuss and quickly resolve other issues and believe that this issue also can be readily and quickly resolved.

Please let me know when the requested meeting has been arranged.

Regards,
Elizabeth Brown

*Elizabeth Anna Brown, Ph.D.
ChemReg International
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192*

*Phone: 703-492-7905
Fax: 703-492-0668
Email: brown@chemreg.com*



165-SS-Chem
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 1, 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JEFFREY PRITCHARD
UNITED PHOSPHORUS INC
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 11-JUN-03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



460085-00

1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
MAIN: 703-492-0445
FAX: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

June 11, 2003

Document Processing Desk
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: George LaRocca (PM 13)

Re: Bifenthrin Technical Insecticide/Miticide (EPA File Symbol 70506-RI)
Response to Agency phone call of June 4 and 5, 2003

Dear George:

On behalf of our client, United Phosphorus, Inc., this letter is in response to phone discussions of June 4 and 5, 2003, with Susan Stanton, where she requested clarification regarding the density of the UPI bifenthrin technical (EPA File Symbol 70506-RI) in comparison to what is reported in the open literature and on file with EPA for the already registered technical grade bifenthrin under EPA Reg. No. 279-3055.

Bifenthrin technical can exist as a very viscous liquid, a waxy solid, or as a crystalline powder (solid), depending upon the purity of the technical grade material (as identified in WHO specifications, Pesticide Manual 11th Ed., copies attached). As part of normal manufacturing processes, a lower grade, crude product is obtained and subjected to purification steps before the final technical grade material is obtained. The extent of the further purification and any crystallization steps will determine the appearance and density of the final technical material. Oily impurities remaining in the technical product contribute to the appearance of the final form. There always is a purity interphase between physical appearance from solid to viscous liquid, which is about 97.5% for Bifenthrin. Above that, the technical bifenthrin is solid, below that it becomes a very viscous liquid, with the waxy semi-solid form intermediate.

CONSULTANTS TO SUCCESSSM

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

Letter to G. LaRocca, June 11, 2003, page 2

The final appearance (form) of the technical material also has a direct bearing upon the density of the technical. Liquids have a higher density than crystalline powders, with waxy solids intermediate between the two.

The purity of the UPI bifenthrin technical is (nominal) 98.2%. It is a crystalline powder. The density of that technical material is 0.4593 g/ml at 27°C, as determined in accordance with OECD Method 109 and CIPAC MT 3.2 "Pycnometer method" (MRID 45838001, in JRF Study No. 2736). Those methods in accordance with OPPTS 830.7300 (June 2002). The validity of those data is confirmed by the enclosed supplementary study conducted at Product Safety Labs (PSL Study No. 13107), in which the pour density was determined to be 0.453 g/ml and the tap density as 0.556 g/ml (OPPTS 830.7300, August 1996).

The currently registered Bifenthrin Technical under EPA Reg. No. 279-3055 is 94.0% (nominal) purity. At that purity level and at the originally registered 89.0% purity (until June 2001), that bifenthrin technical material would be a viscous liquid at 89.0% and a waxy solid/semi-liquid material at 94.0%. The density value for bifenthrin technical as reported in multiple places in the public literature as 1.212 g/ml at 25°C, appears to be associated with the lower purity material, which is a viscous liquid. For example, The Pesticide Manual (11th Ed.) reports the specific gravity/density as 1.21 g/ml, based on older information, as does EXTOWNET (based on the 1988 EPA Fact Sheet No. 177). As a liquid or as a waxy material, the density of these lower purity technical grade bifenthrin products is expected to be higher than that of the high purity UPI product, which is a crystalline powder (solid). This is confirmed by the enclosed study (JRF Study No. 4176), in which the high purity crystalline powder was melted and then determined the density of the melted and solidified material according to appropriate testing methods. The density of the melted, solidified high purity UPI material was found to be 1.2149 g/ml at 20°C. This value may be more appropriately considered as the specific gravity, which for water in the liquid state is 1.000 g/ml.

Thus, the differences in the density is determined by the physical state of the materials, which in turn is determined by the purity. The correct value for the density of the UPI bifenthrin technical is 0.4593 g/ml, for the material as produced (as identified in MRID 45838001). However, the enclosed confirmatory results demonstrate that the density/specific gravity of the product is comparable to the reported literature values when the crystalline nature of the UPI material is modified to the solid form.

We also note, in response to prior Agency comments that the nominal value for the UPI material is outside the certified limits for EPA Reg. No. 279-3055, that the Agency recently approved a 98.65% purity technical bifenthrin (under EPA Reg. No. 51036-390, approval date 2/2/03). The nominal for UPI material is within the certified limits for the latter product, which the Agency deemed substantially similar to the former. As such, and given the enclosed explanation, the Agency should have all information needed to approve the UPI application for registration.

ChemReg

INTERNATIONAL, LLC

Letter to G. LaRocca, June 11, 2003, page 3

There have been significant delays in the Agency's review of this application, although the registrant has responded very rapidly to any questions or requests. We therefore request that the enclosed information be reviewed on a prioritized and rapid basis.

Enclosed with this letter please find EPA Form 8570-1, transmittal bibliography, and three copies of each submitted study.

Regards,

Elizabeth Anne Brown

Elizabeth Anne Brown

Attachments to letter:

1. Interim specification: WHO/IS/TC/415/2001. Technical Bifenthrin
2. The Pesticide Manual, 11th Edition, 1997. Entry for Bifenthrin

cc: United Phosphorus, Inc.

TRANSMITTAL DOCUMENT

Submitter

United Phosphorus, Inc.
423 Riverview Plaza
Trenton, NJ 08611

Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")
(Bifenthrin Technical Insecticide/Miticide 70506-RD)

Transmittal Date

June 11, 2003

Submitted Studies

	MRID	
		Administrative Materials
Document 1:	46008501	Wo, C. 2003. Bifenthrin Technical. Physical and Chemical Characteristics: Density. Unpublished report submitted by United Phosphorus, Inc. PSL Study No. 13107. 10 pages.
Document 2	46008502	Vohra, Y. 2003. Density of Bifenthrin. Unpublished report submitted by United Phosphorus, Inc. JRF Study No. 4176. 15 pages.

Company Official

Elizabeth Anne Brown

Company Name:

ChemReg International, LLC., Authorized Representative for UPI

Company Contact:

Elizabeth Anne Brown

Phone Number:

703-492-7905



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide -- Section I

1. Company/Product Number 70506-RI	2. EPA Product Manager George LaRocca	3. Proposed Classification
4. Company/Product (Name) Blifenthrin Technical Insecticide/Miticide	PM # 33	<input type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment -- Explain below	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> Agency letter dated
	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification -- Explain below	<input checked="" type="checkbox"/> Other -- Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Supplementary Information in response to Agency phone calls of June 4, 5, 2003

Section III

1. Material This Product Will be Packaged In:									
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
*Certification must be submitted		If "Yes" Unit Packaging wgt.		No. per container		If "Yes" Package wgt.		No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container				4. Size(s) Retail Container			5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product		
6. Manner In Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____					

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Elizabeth Anne Brown	Title ChemReg International, LLC Authorized agent	Telephone No. (Include Area Code) 703-492-7905

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law

2. Signature <i>Elizabeth Anne Brown</i>	3. Title ChemReg International, LLC Authorized Agent	(Stamped)
4. Typed Name Elizabeth Anne Brown	5. Date June 11, 2003	

TECHNICAL BIFENTHRIN

Interim specification: WHO/IS/TC/415/2001

1. Specification**1.1 Description**

The material shall consist of homogeneous mixture of technical bifenthrin together with some related manufacturing impurities. It shall be in a form of a light brown to amber viscous liquid, crystalline solid or waxy solid with a very faint slightly sweet odor, free from visible extraneous matter and added modifying agents.

1.2 Chemical and physical requirements

The material sampled¹ from any part of the consignment, (see method WHO/M/1.R1), shall comply with the requirements of section 1.1 and with the following requirements.

1.2.1 Identity test

Where the identity of the active ingredient is in doubt, then it shall comply with at least one additional test (CIPAC method 415/TC/M/2).

1.2.2 Bifenthrin content (g/kg basis)

The bifenthrin content shall be declared (not less than 920 g/kg) and, when determined by the method described in section 2.1, the mean measured content shall not be lower than the declared content.

1.2.3 Acidity

The acidity of the material, when determined by the CIPAC method MT 31 (CIPAC Handbook F, p.96), shall not be higher than 4.0 g/kg calculated as H₂SO₄.

1.2.4 Water content

The water content determined by the method described in WHO/M/7.R1 (equivalent to CIPAC method MT 30.5, CIPAC Handbook J, p.120), shall not be higher than 2.0 g/kg.

¹ Before sampling heat the contents of the container to about 80 °C to melt any crystallized active ingredient, and homogenize by appropriate shaking.

1.3 Packing and marking of packages

The technical bifenthrin shall be packed in suitable clean containers, as specified in the order.

All packages shall bear, durably and legibly marked on the container, the following:

Manufacturer's name
Technical bifenthrin
Batch or reference number and date of test
Net weight of contents
Date of manufacture

and the following minimum cautionary notice:

Bifenthrin is a pyrethroid that acts predominantly on the central nervous system; high dosages have been found to cause tremor and clonic convulsions in experimental animals. A high concentration in air may be irritant to the eyes and contact with the concentrated product may induce a temporary tingling sensation, particularly on the face. It may be hazardous if swallowed. Do not inhale spray mist. Avoid skin contact; wear protective gloves, clean protective clothing, and a face mask (surgical type) when handling the product. Wash hands and exposed skin thoroughly after using.

Keep containers out of reach of children and well away from foodstuffs and animal feed and their containers. If poisoning occurs, call a physician. Treatment is symptomatic.

Bifenthrin is toxic to aquatic wildlife. Avoid accidental contamination of water.

2. Methods of determining chemical and physical properties

2.1 Bifenthrin content

2.1.1 Outline of method

This test method describes the analysis of technical bifenthrin and several of its formulations. Improved column technology and method optimization have yielded a method which give results equivalent or superior to previous methods.

Bifenthrin is determined by comparison to an internal standard, octacosane. A test solution containing a known concentration of octacosane is utilized by comparing instrument response (peak area) of the internal standard to the relative response of bifenthrin, taking into account the amount of sample being analyzed.

2.1.2 Apparatus

Analytical Balance. Capable of accurately weighing to 0.1 mg or equivalent.

Centrifuge.

Gas Chromatograph. Capable of operating over the range 100 to 300°C, fitted with a flame ionization detector and data collection system and if possible an autosampler.

Graduated Cylinder. 500 mL.

Reciprocating Shaker.

Vials, Minimum 40 mL capacity, with poly-lined cap.

Volumetric Pipette.

Magnetic Stirrer and stir bar.

Column. Megabore DB-210, 30 meter length, 0.53 mm internal diameter, film thickness 1 μ m; maximum temperature (isothermal) 200 °C. Available from J&W Scientific, or equivalent.

2.1.3 Reagents

Octacosane, Eastman Kodak Chemical Co or equivalent.

Heptane.

Acetone.

Bifenthrin, Analytical Standard Grade, available from FMC Corporation, Agricultural Chemical Group, Princeton, NJ, USA.

2.1.4 Analytical instrument parameters

Gas Chromatograph parameters (all conditions may be adjusted to optimize results):

Oven Temperature:	205 °C
Injection Port Temperature:	240 °C
Detector Temperature:	300 °C

Data Station Parameters: (all parameters may be modified to optimize results):

Run Time:	8 minutes
Chart Speed:	0.5 cm/min
Zero:	5% full scale

2.1.5 Determination of response factor "RF"

Weigh 0.1 g of the analytical standard, to the nearest 0.001g, and place into a vial.

Prepare an internal standard stock solution by weighting 2.5 g octacosane, to the nearest 0.01 g, and placing it into a bottle with a capacity of at least 1000 mL. To this add 700 mL of heptane and 175 mL of acetone, which have been measured by a graduated cylinder. Mix well using a magnetic stirrer.

Pipette 40 mL of the internal standard stock solution to the vial containing the analytical standard; mix on reciprocating shaker until dissolved.

Inject 1 μ L of the standard solution into the gas chromatograph.

Obtain several chromatograms and measure the peak areas of the internal standard and bifenthrin.

Calculate response factor by the following formula:

$$Rf = \frac{A_{is} \times WT_{std} \times P_{std}}{A_{std} \times WT_{is} \times P_{is}}$$

Where: A_{is} = Area internal standard
 A_{std} = Area bifenthrin
 WT_{std} = Weight of standard
 WT_{is} = Weight of internal standard
 P_{std} = Purity of bifenthrin standard
 P_{is} = Purity of internal standard

2.1.6 Sample preparation

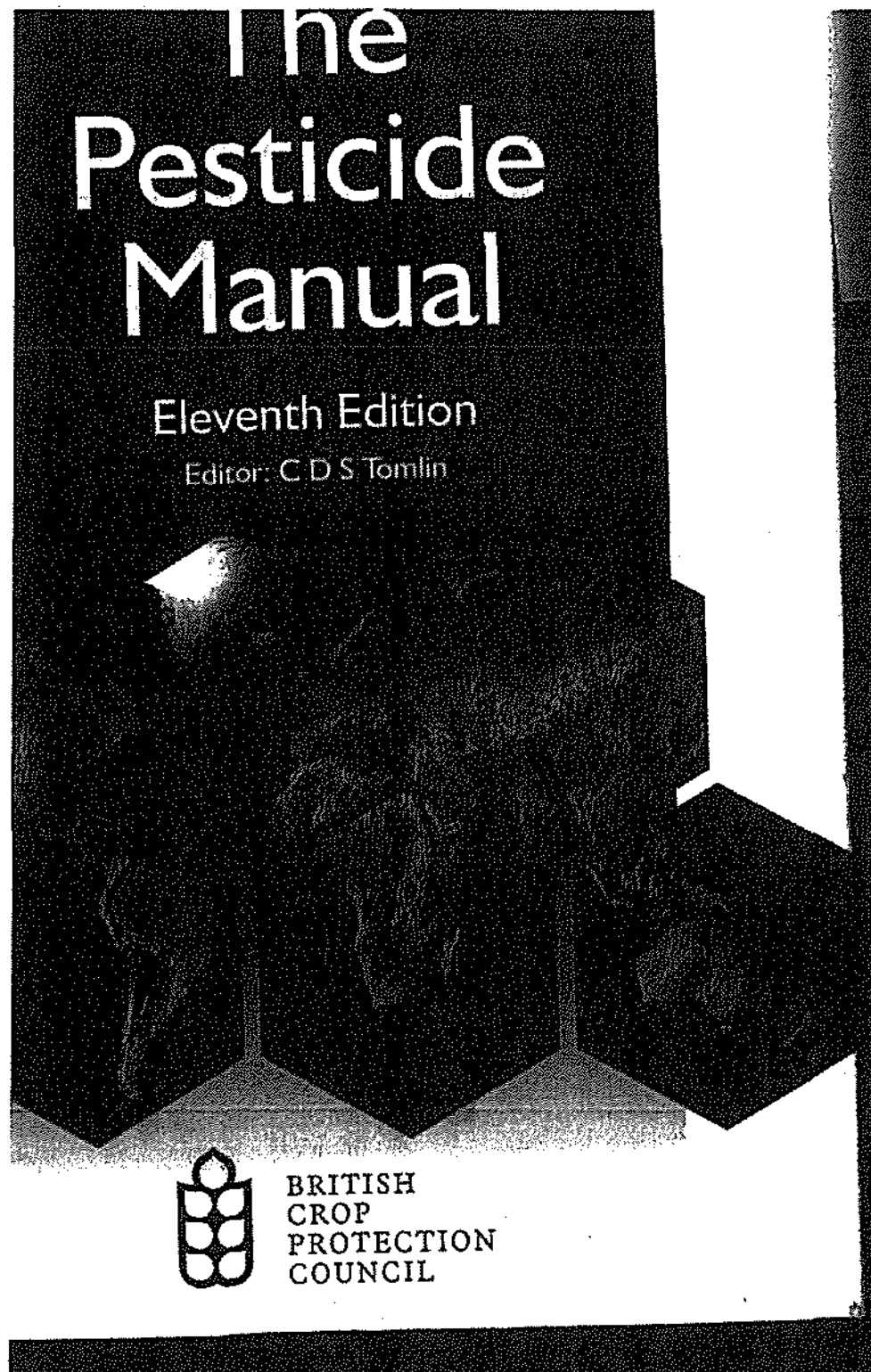
Bifenthrin technical. weight 0.1 g into a vial. Add 40 mL of internal standard stock solution and mix on reciprocating shaker until dissolved.

Inject 1 μ L portions of the sample solutions, obtaining three replicate injections for each. Run a standard injection series after every three or four samples.

Calculate percent (%) active ingredient bifenthrin by the following formula:

$$\% = \frac{A_{spl} \times WT_{is} \times RF \times 100}{A_{is} \times WT_{spl}}$$

Where: A_{spl} = Area of bifenthrin in sample
 WT_{is} = Internal standard weight
RF = Response Factor
 A_{is} = Area of internal standard peak
 WT_{spl} = Sample weight

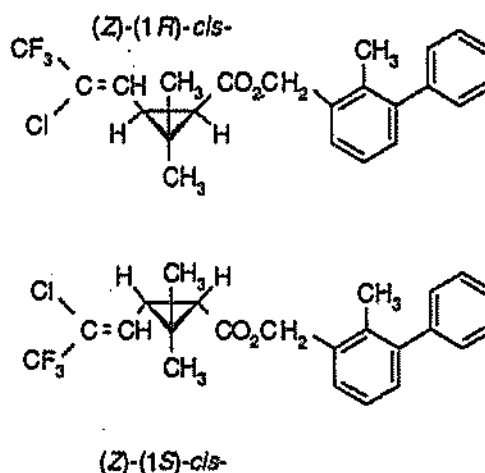


1997

bifenthrin

Insecticide, acaricide

pyrethroid



NOMENCLATURE

Common name bifenthrin (BSI, ANSI, draft E-ISO); bifenthrine ((f) draft F-ISO)

IUPAC name 2-methylbiphenyl-3-ylmethyl (Z)-(1*RS*,3*RS*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

Roth: 2-methylbiphenyl-3-ylmethyl (Z)-(1*RS*)-*cis*-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

Chemical Abstracts name (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate

CAS RN [82657-04-3] **Development codes** FMC 54 800

Official codes OMS 3024

PHYSICAL CHEMISTRY

Composition Material contains ≥97% *cis*- isomer, ≤3% *trans*- isomer.

Mol. wt. 422.9 **M.f.** C₂₃H₂₂ClF₃O₂ **Form** Viscous liquid; crystalline or waxy solid **M.p.** 51–66 °C **V.p.** 0.024 mPa (25 °C) **K_{ow} logP** >6 **S.g./density** 1.210 (25 °C)

Solubility In water, 0.1 mg/l. Soluble in acetone, chloroform, dichloromethane, diethyl ether, and toluene. Slightly soluble in heptane and methanol. **Stability** Stable for 2 y at 25 °C and 50 °C (tech.). In natural daylight DT₅₀ 255 d, stable 21 d at pH 5–9 (21 °C). **F.p.** 165 °C (Tag open cup); 151 °C (Pensky Martens closed cup)

COMMERCIALISATION

History Insecticide and acaricide reported by H. J. H. Doel et al. (Meded. Fac. Landbouwwet. Rijksuniv. Gent, 1984, 49, 929) and A. R. Crossman et al. (ibid., p. 939). Introduced by FMC Corp. **Manufacturers** FMC

#14685

DP BARCODE: D288051

CASE: 072204
SUBMISSION: S628277

DATA PACKAGE RECORD
BEAN SHEET

DATE: 01/29/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 166 RESB NEW PRO-OC-MIN CHG
RANKING : 10 POINTS ()
CHEMICALS: 128825 Bifenthrin (ANSI) 99.4000%

ID#: 070506-RI BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE
COMPANY: 070506 UNITED PHOSPHORUS INC
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: SUSAN STANTON 703-305-5218 ROOM: CM2 237
RECEIVED DATE: 01/15/03 DUE OUT DATE: 07/14/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 288051 EXPEDITE: N DATE SENT: 01/29/03 DATE RET.: / /
CHEMICAL: 128825 Bifenthrin (ANSI)
DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y 5-6-03
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 06/18/03
DIV : RD / / / / NEGOT DATE: / /
BRAN: TRB / / / / PROJ DATE: / /
SECT: CHEM / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Attn: Resubmission in Response to Linda Kutney's 12/12/02 review (D285142)

On behalf of United Phosphorus, ChemReg has submitted additional data/information and a corrected CSF to address deficiencies noted in Linda's original review. Please review the company's response, including the new CSF and data (MRID#458380-01), and determine whether it adequately addresses TRB's concerns. Copies of the cover letter, data and CSF are attached, along with TRB's original review and the company's original product chemistry submission (for reference.).

If you need anything else, please give me a call.

Thanks,
Susan Stanton

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------

DATE: May 20, 2003

SUBJECT: Product Chemistry Review of Bifenthrin Technical

FROM: Linda L. Kutney
Product Chemistry Team
Technical Review Branch/RD (7505C)

Linda L. Kutney
5/21/03

S/R
5/21/03

TO: Cynthia Giles-Parker, Susan Stanton PM 3
Insecticide Branch/ RD (7505C)

DP BARCODE: D288051
EPA REG. NO.: 70506-RI
REGISTRANT: United Phosphorus, Inc.
USE: Insecticide

INTRODUCTION:

United Phosphorus, Inc. has submitted additional product chemistry data to support the registration of "Bifenthrin Technical. Insecticide/Miticide" in response to TRB's 12/11/02 review, D285142. The revised proposed basic CSF is dated 1/9/03.

This proposed label is for insecticide/miticide non-food use, including as a termiticide and soil contact nonfumigation treatment, as wood treatment and protection, as outdoor insect control, on ornamental plants, trees, shrubs and woody vines, residential lawns and for indoor insect control, spot or crack and crevice treatment in non-food areas. Use in food or feed areas is prohibited. The product chemistry data has been submitted under 45838001 and previously under MRIDs 45654401, 456544 02 and 45654403.

In their letter of 4/8/02, United Phosphorus claimed similarity to FMC's Bifenthrin Technical, Reg. No. 279-3055, containing 94.0% of Bifenthrin ai, and a minimum of 97% cis isomers and a maximum of 3% of trans isomers, as listed on the label accepted 6/21/01. No minimum of trans Bifenthrin isomers was included on the approved label.

SUMMARY OF FINDINGS:

1. The description of materials used to produce the product satisfies the data requirements of guideline 830.1600 (40CFR§ 158.160).
2. The description of production process satisfies the data requirements of guideline reference 830.1620 (40CFR§158.162).
3. The discussion on the formation of impurities satisfies the data requirements of guideline reference 830.1670 (40CFR§158.167).
4. Data requirements for oxidation-reduction, flammability, explosability, pH, melting point, boiling point, density, and dissociation constant now satisfy the data requirements of guideline references 830.6314, 830.6315, 830.6316, 830.7000, 830.7200, 830.7220, 830.7300, and 830.7370, respectively.
5. The density and pH are now included in blocks 7 and 8 of the revised CSF, in agreement with the study results, as required.
6. The "non-applicable" flash point given in block 9 of the CSF is now supported by study results, as required.
7. The chemical name for bifenthrin is now included in column 10 of the CSF, as required.
8. The minimum and maximums listed in column 10 for cis and trans isomers of bifenthrin correspond to the fractions of total bifenthrin. The minimum amount of cis isomer given in column 14b and the maximum value of trans isomer given in column 14a of the CSF are calculated correctly.
9. The Analytical Method (guideline reference 830.1800, 40CFR158.180) indicates that cis and trans bifenthrin is adequately separated and quantitated.
10. The Registrant has agreed that samples will be submitted to the Agency laboratory upon registration of the product. Guideline 830.1900, (40CFR158.190) is satisfied.

CONCLUSION:

TRB has determined that Bifenthrin Technical Insecticide/Miticide is not substantially similar to FMC's Bifenthrin Technical, Reg. No. 279-3055, from a physical chemistry standpoint due partly to the fact that it has a density of 3.83 lb/gal. as opposed to 10.5 lb/gal for FMC's Bifenthrin Technical, Reg. No. 279-3055. In addition the minimum concentration of the active cis portion of Bifenthrin does not fall between the UCL and LCL for the cited, registered product.

The proposed CSF, dated 2/8/02 is acceptable with the comment we recommend column 10 of the CSF be revised to list the parenthetical expressions as follows:

- that the cis isomer include the statement '97% minimum of total Bifenthrin' and the
- trans isomer include the statement '3% maximum of total Bifenthrin' for additional clarity.

CSF OK
as is
8/1/03

For full registration, United Phosphorus must submit the following Subgroup B physical chemical studies (See 40CFR Section 190):

STUDY:

GUIDELINE REFERENCE #:

Storage stability

830.6317

Corrosion Characteristics

830.6320

The following product chemistry requirements are still not satisfied:

Partition coefficient (n-oct/water)shake flask method

830.7550

Water Solubility column elution method, shake flask method

830.7840

Solubility in organic solvents

BARCODE: D285142; Reg. No. 70506-R1 PRODUCT: Bifenthrin Tech. Insecticide/Miticide

830.1550. Product Identity:

Common Name: Bifenthrin Technical

Chemical Name: "(2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate."

CAS No.: 82657-04-3 for cis isomer, 83322-02-3 for trans isomer

PC Code No.: 128825 for cis and trans mix

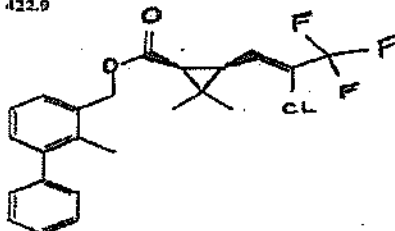
Empirical formula: C₂₃ H₂₂ Cl F₃ O₂

Molecular Weight: 422.9 g/Mole

Structural formula and additional product identity data (from MRID 456544-01)

Trade Name:
Molecular Formula:
Molecular Weight:
Structural Formula:

Bifenthrin Technical
C₂₃H₂₂ClF₃O₂
422.9



BARCODE: D285142; Reg. No. 70506-RI PRODUCT: Bifenthrin Tech. Insecticide/Miticide

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Table 1: Manufacturing and Impurity Data for United Phosphorus 's Bifenthrin T/TGAI.				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency
830.1550	Product identity and composition	CSF 1/9/03 45654401	A	Nominal concentrations and certified limits for the AI & all the impurities provided in the CSF agree with the study results in MRID 45654401.
830.1600	Description of materials used to produce product	45654401	A	The product specification sheets (MSDS) for the starting materials were submitted.
830.1650	Description of production process	45654401	A	The registrant provided detailed information about the synthesis of the technical. Amounts of each starting material and the conditions of the reaction were provided.
830.1670	Discussion of formation of impurities	45654401	A	The registrant provided the required information on the formation of impurities.
830.1700	Preliminary analysis	45654401	A	Method validation indicates that the method is adequate for the determination of the ai. Analysis was conducted on 5 production batches of the ai.
830.1750	Certified limits	1/9/03 CSF	A	The certified limits given in the CSF are in agreement with the study.

Table 1: Manufacturing and Impurity Data for United Phosphorus 's Bifenthrin T/TGAI.				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency
830. 1800	Enforcement analytical method	45654401	A	"HPLC Method for Determination of Bifenthrin" Compilation Report UPI-Bifentec-A., dated 3/19/02. Bifenthrin test sample is dissolved in HPLC grade acetonitrile, and an aliquot is subjected to reverse phase LC. The cis and trans isomers are combined in a single LC peak and then separate quantitation accomplished using UV detection at 254 nm, using external standard quantitation.
830. 1900	Submission of Samples	1/15/03 Chem Reg. Letter	N	Samples will be provided prior to registration.
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.				

BARCODE: D285142; Reg. No. 70506-RI PRODUCT: *Bifenthrin* Tech. Insecticide/Miticide

Table 2: Physical and Chemical Properties for the <i>BIFENTHRIN</i> technical .				
GLN	Requirement	MRID	Status ¹	Result or Deficiency
830.6302	Color	45654402	A	White
830.6303	Physical state	45654402	A	Solid Powder
830.6304	Odor	45654402	A	None
830.6313	Stability to normal & elevated temperatures, metals, and metal ions.	45654403 Letter of 1/15/03	A	Waiver Granted. Material is stored and shipped in HDPE-not in contact with metal.
830.6314	Oxidation Reduction: chemical incompatibility	45654401	A	Not reported to contain oxidizing or reducing agents.
830.6315	Flammability	45654401	A	Not flammable
830.6316	Explosibility	45654401	A	Does not contain explosive components
830.6317	Storage stability	45654403	N	No significant change noted after storage at 54 ± 2 C for 14 days. Stability Testing at 3, 6, 9, 12, 18, and 24 months is required for full registration.
830.6319	Miscibility	-	NA	Not a liquid at 20 C.

Table 2: Physical and Chemical Properties for the <i>BIFENTHRIN</i> technical .				
GLN	Requirement	MRID	Status ¹	Result or Deficiency
830.6320	Corrosion characteristics	45654403	N	No significant change was noted after storage at 54 ± 2 C for 14 days. Corrosion Characteristics Testing at 3,6, 9, 12, 18, and 24 months is required for full registration.
830.6321	Dielectric Breakdown Voltage	-	A	Not Required. Not used around electrical equipment.
830.7000	pH	45654401	A	6.52 ± 0.03
830.7050	UV/Visible absorption	-	A	NA Not a liquid at 20 C.
830.7100	Viscosity	-	A	NA Not a liquid at 20 C.
830.7200	Melting point/range	45654401	A	68-71 C
830.7220	Boiling point/range	-	A	NA Not a liquid at 20 C.
830.7300	Density/relative density/bulk density	45654401	A	Density $0.4593 = 3.83$ lb/gal Specific gravity 0.3762
830.7370	Dissociation constant in water	45654401	A	NA Product does not ionize in water
830.7550	Partition coefficient (n-octanol/water) shake flask method	-	N	
830.7840	Water solubility: column elution method; shake flask method Solubility in organic solvents	-	N	

Table 2: Physical and Chemical Properties for the <i>BIFENTHRIN</i> technical .				
GLN	Requirement	MRID	Status ¹	Result or Deficiency
830.7950	Vapor pressure	-	NA	Not a liquid at 20 C
¹ A = Acceptable; N = Not Acceptable (see Deficiency); NA = Not applicable. ² For example, "brown" for 830.6302; "155° C" for 830.7200.				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

January 8, 2003

MEMORANDUM

Product Name: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE

EPA File Symbol: 70506-RI

DP Barcode: D285143

Case No: 072204

Submission: S620915

Chemical: 128825 Bifenthrin

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
1-8-2003

To: Susan Stanton/Arnold Layne, PM 03
Insecticide-Rodenticide Branch
Registration Division (7505C)

Registrant: UNITED PHOSPHORUS INC.

ACTION REQUESTED: "United Phosphorus, Inc. has submitted an application to register a new bifenthrin technical product, claiming substantial similarity to FMC's registered technical. They wish to rely on acute toxicity data for FMC's technical to fulfill all of the acute tox requirements except oral and dermal toxicity. They have submitted their own oral toxicity (MRID#456544-04) and dermal toxicity (MRID#456544-05) studies. Please determine whether the submitted studies are acceptable and whether they may rely on FMC's data for the other acute toxicity requirements (i.e., is the product substantially similar to FMC's registered technical). Copies of the labels and CSFs for the new product and cited product (EPA Reg. No. 279-3055) are included for your information and review. Note: I was unable to locate a review of the cited acutes; however, I have a very recent draft risk assessment for bifenthrin from HED which includes the acute tox profile for bifenthrin technical based on the cited studies, except the inhalation study..."

BACKGROUND: According to the copy of the proposed label received by TRB, this product [EPA File Symbol: 70506-R1: Bifenthrin Technical Insecticide/Miticide] has the following ingredient declaration:

Active Ingredient:

Bifenthrin (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate*99.4%

Inert Ingredients:.....0.6%

As part of this package, TRB has received the following two acute toxicity studies: acute oral LD50 in rats (MRID 45654404); and acute dermal LD50 in rats (MRID 45654405).

COMMENTS AND RECOMMENDATIONS:

1. The two submitted acute toxicity studies (MRIDs 45654404 and 45654405) have been reviewed and have been classified as acceptable.
2. While the dermal toxicity study (MRID 45654405) has been classified as acceptable, The report states that in one preliminary range finding study mortality (in 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg) was observed; this was followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg...and the percent mortality observed was 0, 25 and 25, respectively." This information is considered as 6(a)(2) data [refer to CFR40 §152.125], and a more detailed report (which should include how the test material was applied and differences, if any, between the protocol(s) used in the preliminary studies and the final study) should be submitted to the Agency.
3. From the summary listing of the acute toxicity profile of Bifenthrin, it is noted that a primary eye irritation study in MRID 00132522 indicates the existing (FMC) registration for technical bifenthrin is in toxicity category IV by this exposure route. Because there may be subtle physical and/or chemical differences between the two technicals, TRB recommends that, in lieu of an actual eye irritation study for the proposed United Phosphorus Bifenthrin Technical, that it be placed in toxicity category III in terms of eye irritation potential. This is consistent with the proposed labeling for this product (which includes a FIRST AID statement for eye exposure, as well as the precautionary statement: "Causes moderate eye irritation." The remainder of the precautionary labeling (addressing inhalation toxicity, dermal irritation and dermal sensitization potentials) should then be consistent with the existing labeling for FMC technical bifenthrin.

4. Based on the results of the reviewed acute toxicity studies, as well as the considerations indicated above, the following is the acute toxicity profile for EPA File Symbol 70506-RI BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE:

Acute Oral LD50	Acceptable	Tox. Cat. II (MRID 45654404)
Acute Dermal LD50	Acceptable	Tox. Cat. III (MRID 45654405)
Acute Inhalation LC50	Cited	Tox. Cat. III(?)*
Primary Eye Irritation	Cited	Tox. Cat. III**
Primary Dermal Irritation	Cited	Tox. Cat. IV
Dermal Sensitization	Cited	Negative

*Summary sheet indicates no existing inhalation toxicity studies. Label for this proposed product is consistent with toxicity category III, and this is acceptable if the FMC product is also in toxicity category III by this exposure route.

**Summary sheet indicates the FMC product is in toxicity category IV by this exposure route. As slight physical and/or chemical differences may impact on eye irritation potential, TRB recommends that, in lieu of a primary eye irritation study on the United Phosphorus Technical Bifenthrin, that it be assigned to toxicity category III by this exposure route. This is consistent with the labeling proposed for this product by United Phosphorus.

5. Based on the acute toxicity profile given above and based on the proposed label use directions, the following is the precautionary labeling for this product, as obtained from the Label Review System:

PRODUCT ID #: 070506-00018

PRODUCT NAME: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:**If swallowed:**

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100, formerly §81-1)

Product Manager: 03
MRID No.: 45654404

Reviewer: Byron T. Backus, Ph.D.

CITATION: Tiwari, V.K. Acute Oral Toxicity Study of Bifenthrin Technical in Rats. JRF Study No. 3415. Unpublished study prepared by Department of Toxicology, Jai Research Foundation, Valvada 396108, Gujarat, India. Final Report Date: FEB-9-2002. MRID 45654404.

SUBMITTER & SPONSOR: UNITED PHOSPHORUS INC.

TEST MATERIAL: Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

SPECIES: Rat, Wistar

AGE(at dosing): young adult, 9 weeks

WEIGHT (presumably fasted): Males: 204-270 g; Females: 194-235 g

SOURCE: Breeding facility, Jal Research Foundation

EXECUTIVE SUMMARY: *In an acute oral toxicity study (MRID 45654404), fasted (17+ hrs) young adult (9 week old) Wistar rats (5 males and 5 females/dose level) were orally gavaged with Bifenthrin Technical (a white powder containing 99.2% active) in peanut oil at a constant dose volume of 10 mL/kg. Doses in the main study were 0 (vehicle only), 50, 79 and 125 mg/kg.*

At 50 mg/kg 0/5M & 2/5F died; at 79 mg/kg 4/5M & 2/5F died; at 125 mg/kg 5/5M & 3/5F died. All deaths were within 24 hours of dosage. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions in all animals. Survivors were generally normal by Day 3. All survivors had weight gains from Day 0 to Day 7 and again from Day 7 to Day 14, with the exception of one 50 mg/kg female who had the same bodyweight on Day 7 and Day 14.

The rats which died showed findings which included mottling or congestion of the liver and mottling or congestion of the lungs. 13/16 rats found dead had pulmonary congestion, and it is reported that this is a common finding in dead animals with no particular pathological significance. Findings in terminally sacrificed animals were categorized as spontaneous/accidental.

Oral LD50 Males = 66.19 (95% C.L. of 54.48 to 77.90) mg/kg

Oral LD50 Females = 91.89 (95% C.L. of 26.67 to 316.63) mg/kg

Oral LD50 Combined = 74.90 (95% C.L. of 57.29 to 97.92) mg/kg

Bifenthrin technical, a white powder containing 99.2% active ingredient, is in toxicity category II in terms of oral toxicity.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

Procedure (Including deviations from 870.1100): Following preliminary range-finding testing, "four groups of rats, each dose group comprising 5 males and 5 females, were randomly selected and three groups were given a single dose of bifenthrin technical at dose levels of 50, 79 and 125 mg/kg... As the test substance is insoluble in water, it was suspended in peanut oil at the required concentrations prior to dosing. The dose solution was stirred to ensure that there were no visible precipitates. Another group was administered peanut oil at a constant dose volume of 10 mL/kg...as control. A dose volume of 10 mL/kg body weight was calculated for each rat. All animals were dosed once by gavage (day 0) using a metal cannula... Animals were deprived of feed for seventeen hours and fifteen minutes prior to dosing and then three hours after dosing."

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Total
0 (vehicle only)	0/5	0/5	0/10
50	0/5	2/5	2/10
79	4/5	2/5	6/10
125	5/5	3/5	8/10

Observations: All deaths were within 24 hours of dosage. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions in all animals. Survivors were generally normal by Day 3. All survivors had weight gains from Day 0 to Day 7 and again from Day 7 to Day 14, with the exception of one 50 mg/kg female who had the same bodyweight on Day 7 and Day 14.

Gross Necropsy: The rats which died showed findings which included mottling or congestion of the liver and mottling or congestion of the lungs. 13/16 rats found dead had pulmonary congestion, and it is reported that this is a common finding in dead animals with no particular pathological significance. Findings in terminally sacrificed animals were categorized as spontaneous/accidental.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200, formerly §81-2)

Product Manager: 03
MRID No.: 45654405

Reviewer: Byron T. Backus, Ph.D.

CITATION: Tiwari, V.K. Acute Dermal Toxicity Study of Bifenthrin Technical in Rats. JRF Study No. 3416. Unpublished study prepared by Department of Toxicology, Jai Research Foundation, Valvada 396108, Gujarat, India. Final Report Date: FEB-9-2002. MRID 45654405.

SUBMITTER & SPONSOR: UNITED PHOSPHORUS INC.

TEST MATERIAL: Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

SPECIES: Rat, Wistar

AGE(at dosing): not stated; presumably young adult (consistent with body weight data)

WEIGHT: Males: 229-282 g; Females: 216-259 g

SOURCE: Breeding facility, Jai Research Foundation

EXECUTIVE SUMMARY: *In an acute dermal toxicity study (MRID 45654405), groups of 5M & 5F young adult Wistar rats were dermally exposed for 24 hrs (occluded exposure) to either 2000 mg/kg Bifenthrin technical (a white powder with 99.2% purity) mixed with an unspecified amount of peanut oil "to give a slurry," or to 0.2 mL of peanut oil alone.*

There were no mortalities. 9/10 of the rats exposed to bifenthrin showed symptoms (tremors) on Day 3, and two of these rats (both males) also had tremors and piloerection on Days 4-5. All rats were normal from Day 6 through Day 14. All 5 males had bodyweight gains in the period from Day 0 to Day 7, but all 5 females had weight losses during this period; 5/5 males and 4/5 females had bodyweight gains in the period from Day 7 to Day 14.

Necropsy findings (pinpoint lung hemorrhages in one male; bilateral uterine hydrometra in one female) were considered spontaneous and unrelated to exposure to bifenthrin.

The report states that in one preliminary range finding study mortality (in 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg) was observed; this was followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg...and the percent mortality observed was 0, 25 and 25, respectively." This information is considered as 6(a)(2) data, and a detailed report should be submitted to the Agency.

Dermal LD50 Males > 2000 mg/kg (0/5 died at this dose level)

Dermal LD50 Females > 2000 mg/kg (0/5 died at this dose level)

Dermal LD50 Combined > 2000 mg/kg (0/10 died at this dose level)

Bifenthrin technical, a white powder containing 99.2% active, is in toxicity category III in terms of dermal toxicity, based on the dermal LD50 > 2000 mg/kg.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

Procedure [including deviations from 870.1200]: "A dose range finding study for bifenthrin technical was performed using four (2 male and 2 female) animals per group. The per cent mortality observed were 25, 25 and 50 at the dose levels of 500, 1000 and 2000 mg/kg body weight. Based on above results, main study was conducted at the dose level of 700, 1260 and 2268 mg/kg body weight. As sufficient mortality was not observed at the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg body weight and the per cent mortality observed was 0, 25 and 25, respectively. Therefore, the study was conducted as a limit study using 2000 mg/kg body weight."

"Depending on the result of the range finding study, two groups of rats, comprising 5 males and 5 females per group, were randomly selected...and one group was given dermal application of bifenthrin technical at the dose level of 2000 mg/kg body weight. As bifenthrin technical was insoluble in water, the measured/calculated quantity of bifenthrin technical was mixed with peanut oil, to give a slurry, for even application on the exposed part of the skin. The other group of ten animals (5 male and 5 female), which served as control, was simultaneously treated with 0.2 mL of peanut oil and maintained in similar experimental conditions. The test substance was held in contact with the skin with a porous gauze dressing (not more than 8 ply) and Medi tape 330 hypo-allergic surgical tape...throughout the 24 hour of exposure period to prevent evaporation of the test substance and to ensure that the animals did not ingest it. At the end of the exposure period, the residual test substance was removed using cotton moistened with distilled water."

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
0	0/5	0/5	0/10
2000	0/5	0/5	0/10

Observations: None of the rats showed any clinical signs from Day 0 to Day 2. 5/5 males and 4/5 females had tremors on Day 3; all but 2 males had recovered the following day. The 2 males showed tremors and piloerection on Days 4 and 5, but were normal on Day 6. All 5 males gained weight in the period from Day 0 to Day 7, while all 5 females lost weight during this same period. All males continued to gain weight in the period from Day 7 to Day 14, but one female lost weight during this period and 3 others, although gaining some weight, had still lost a few grams from their initial (Day 0) weight.

Gross Necropsy: 2000 mg/kg: 3/5 males and 4/5 females had NAD (No abnormalities detected). One male had pin-point hemorrhages (mild) of the lungs; the other male had blotched kidneys and a few pin-point hemorrhages of the lungs. One female had partial consolidation in the right cranial lobe of the lung.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D285143
2. PC CODE: 128825 Bifenthrin
3. CURRENT DATE: January 8, 2003
4. TEST MATERIAL: EPA File Symbol 70506-RI; Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/ra/ Jai Research Foundation Gujarat India/Study No. 3415/FEB-9-2002	45654404	LD ₅₀ (M) = 66.2 (54.5-77.9) mg/kg; LD ₅₀ (F) = 91.9 (26.7-316.6)mg/kg; LD ₅₀ (Combined) = 74.9 (57.3-97.9) mg/kg. Dose levels: 50, 79 & 125 mg/kg of test material in peanut oil at a constant dose volume of 10 mL/kg. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions. Survivors were generally normal by Day 3.	II	A
Acute Dermal Toxicity/ra/ Jai Research Foundation Gujarat India/Study No. 3416/FEB-9-2002.	45654405	There were no mortalities among 5M & 5F dermally exposed to 2000 mg/kg. 9/10 rats had tremors on Day 3, and 2 of these (both males) had tremors and piloerection on Days 4-5. All rats were normal Days 0-2, Days 6-15. All 5M had bodyweight gains in the period from Day 0 to Day 7, but all 5F had weight losses; 5/5 males and 4/5 females had bodyweight gains in the period from Day 7 to Day 14. Necropsy findings (pinpoint lung hemorrhages in one male; bilateral uterine hydrometra in one female) were considered spontaneous and unrelated to exposure to bifenthrin. Report states that in a preliminary range finding study 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg died; followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg... and the percent mortality observed was 0, 25 and 25, respectively."	III	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated

JAN 21 2003

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

UNITED PHOSPHOROUS, INC.
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/15/03. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

TRANSMITTAL DOCUMENT

Submitter

United Phosphorus, Inc

United Phosphorus, Inc.
740 Springdale Drive
Suite 204
Exton, PA 19341

ChemReg International, LLC*
2239-H Tacketts Mill Drive
Lake Ridge, VA 22192-3026

*ChemReg International is the authorized representative for United Phosphorus, Inc.

Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")
(Bifenthrin Technical Insecticide/Miticide 70506-RI)

Transmittal Date

January 13, 2003

Submitted Studies

	MRID	
		Administrative Materials
Document 1:	45838001	Brown, E.A. January 9, 2003. Bifenthrin Technical Insecticide. Physical & Chemical Properties (Group B). Compilation Report No. UPI-BIFTECH-B.

Company Official

Elizabeth Anne Brown

Company Name:

ChemReg International, LLC., Authorized Representative for UPI

Company Contact:

Elizabeth Anne Brown

Phone Number:

703-492-7905

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70506-R1	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bifenthrin Technical Insecticide/Miticide	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated Dec. 12, 2002	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Elizabeth Anne Brown		Title ChemReg International, LLC Authorized agent		Telephone No. (Include Area Code) 703-492-7905	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Elizabeth Anne Brown</i>		3. Title ChemReg International, LLC Authorized Agent			
4. Typed Name Elizabeth Anna Brown		5. Date January 15, 2003			

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (Original) Yellow - Applicant Copy

DP BARCODE: D285143

CASE: 072204
SUBMISSION: S620915

DATA PACKAGE RECORD
BEAN SHEET

DATE: 08/30/02
Page 1 of 2

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 166 RESB NEW PRO-OC-MIN CHG
RANKING : 10 POINTS ()
CHEMICALS: 128825 Bifenthrin (ANSI) 99.4000%

ID#: 070506-RI BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE
COMPANY: 070506 UNITED PHOSPHORUS INC
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: SUSAN STANTON 703-305-5218 ROOM: CM2 237
RECEIVED DATE: 08/30/02 DUE OUT DATE: 02/26/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 285143 EXPEDITE: N DATE SENT: 08/30/02 DATE RET.: / /
CHEMICAL: 128825 Bifenthrin (ANSI)
P TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT	ADMIN DUE DATE: 12-8-02
DIV : RD	/	/	/	/	01/17/03
BRAN: TRB	/	/	/	/	NEGOT DATE: / /
SECT: TOX	/	/	/	/	PROJ DATE: / /
REVR :	/	/	/	/	
CONTR:	/	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

United Phosphorus, Inc. has submitted an application to register a new bifenthrin technical product, claiming substantial similarity to FMC's registered technical. They wish to rely on acute toxicity data for FMC's technical to fulfill all of the acute tox requirements except oral and dermal toxicity. They have submitted their own oral toxicity (MRID#456544-04) and dermal toxicity (MRID#456544-05) studies. Please determine whether the submitted studies are acceptable and whether they may rely on FMC's data for the other acute toxicity requirements (i.e., is the product substantially similar to FMC's registered technical). Copies of the labels and CSFs for the new product and cited product (EPA Reg. No. 279-3055) are included for your information and review. Note: I was unable to locate a review of the cited acutes; however, I have a very recent draft risk assessment for bifenthrin from HED which includes the acute tox profile for bifenthrin technical based on the cited studies, except the inhalation study. I can't find any information on the cited inhalation study. A copy of the acute toxicity table from HED's draft memo is included for your information.

Thanks,
Susan Stanton

DP BARCODE: D285143

CASE: 072204 DATA PACKAGE RECORD (CONTINUED)
SUBMISSION: S620915 BEAN SHEET

DATE: 08/30/02
Page 2 of 2

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
285142	TRB/CHEM	08/30/02	01/17/03	Y	Y	Y



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

January 8, 2003

MEMORANDUM

Product Name: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE
EPA File Symbol: 70506-RI
DP Barcode: D285143
Case No: 072204
Submission: S620915
Chemical: 128825 Bifenthrin

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
1-8-2003

To: Susan Stanton/Arnold Layne, PM 03
Insecticide-Rodenticide Branch
Registration Division (7505C)

Registrant: UNITED PHOSPHORUS INC.

ACTION REQUESTED: "United Phosphorus, Inc. has submitted an application to register a new bifenthrin technical product, claiming substantial similarity to FMC's registered technical. They wish to rely on acute toxicity data for FMC's technical to fulfill all of the acute tox requirements except oral and dermal toxicity. They have submitted their own oral toxicity (MRID#456544-04) and dermal toxicity (MRID#456544-05) studies. Please determine whether the submitted studies are acceptable and whether they may rely on FMC's data for the other acute toxicity requirements (i.e., is the product substantially similar to FMC's registered technical). Copies of the labels and CSFs for the new product and cited product (EPA Reg. No. 279-3055) are included for your information and review. Note: I was unable to locate a review of the cited acutes; however, I have a very recent draft risk assessment for bifenthrin from HED which includes the acute tox profile for bifenthrin technical based on the cited studies, except the inhalation study..."

BACKGROUND: According to the copy of the proposed label received by TRB, this product [EPA File Symbol: 70506-RI: Bifenthrin Technical Insecticide/Miticide] has the following ingredient declaration:

Active Ingredient:

Bifenthrin (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate*.....99.4%

Inert Ingredients:.....0.6%

As part of this package, TRB has received the following two acute toxicity studies: acute oral LD50 in rats (MRID 45654404); and acute dermal LD50 in rats (MRID 45654405).

COMMENTS AND RECOMMENDATIONS:

1. The two submitted acute toxicity studies (MRIDs 45654404 and 45654405) have been reviewed and have been classified as acceptable.
2. While the dermal toxicity study (MRID 45654405) has been classified as acceptable, The report states that in one preliminary range finding study mortality (in 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg) was observed; this was followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg...and the percent mortality observed was 0, 25 and 25, respectively." This information is considered as 6(a)(2) data [refer to CFR40 §152.125], and a more detailed report (which should include how the test material was applied and differences, if any, between the protocol(s) used in the preliminary studies and the final study) should be submitted to the Agency.
3. From the summary listing of the acute toxicity profile of Bifenthrin, it is noted that a primary eye irritation study in MRID 00132522 indicates the existing (FMC) registration for technical bifenthrin is in toxicity category IV by this exposure route. Because there may be subtle physical and/or chemical differences between the two technicals, TRB recommends that, in lieu of an actual eye irritation study for the proposed United Phosphorus Bifenthrin Technical, that it be placed in toxicity category III in terms of eye irritation potential. This is consistent with the proposed labeling for this product (which includes a FIRST AID statement for eye exposure, as well as the precautionary statement: "Causes moderate eye irritation." The remainder of the precautionary labeling (addressing inhalation toxicity, dermal irritation and dermal sensitization potentials) should then be consistent with the existing labeling for FMC technical bifenthrin.

4. Based on the results of the reviewed acute toxicity studies, as well as the considerations indicated above, the following is the acute toxicity profile for EPA File Symbol 70506-RI BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE:

Acute Oral LD50	Acceptable	Tox. Cat. II (MRID 45654404)
Acute Dermal LD50	Acceptable	Tox. Cat. III (MRID 45654405)
Acute Inhalation LC50	Cited	Tox. Cat. III(?)*
Primary Eye Irritation	Cited	Tox. Cat. III**
Primary Dermal Irritation	Cited	Tox. Cat. IV
Dermal Sensitization	Cited	Negative

*Summary sheet indicates no existing inhalation toxicity studies. Label for this proposed product is consistent with toxicity category III, and this is acceptable if the FMC product is also in toxicity category III by this exposure route.

**Summary sheet indicates the FMC product is in toxicity category IV by this exposure route. As slight physical and/or chemical differences may impact on eye irritation potential, TRB recommends that, in lieu of a primary eye irritation study on the United Phosphorus Technical Bifenthrin, that it be assigned to toxicity category III by this exposure route. This is consistent with the labeling proposed for this product by United Phosphorus.

5. Based on the acute toxicity profile given above and based on the proposed label use directions, the following is the precautionary labeling for this product, as obtained from the Label Review System:

PRODUCT ID #: 070506-00018

PRODUCT NAME: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:**If swallowed:**

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100, formerly §81-1)

Product Manager: 03
MRID No.: 45654404

Reviewer: Byron T. Backus, Ph.D.

CITATION: Tiwari, V.K. Acute Oral Toxicity Study of Bifenthrin Technical in Rats. JRF Study No. 3415. Unpublished study prepared by Department of Toxicology, Jai Research Foundation, Valvada 396108, Gujarat, India. Final Report Date: FEB-9-2002. MRID 45654404.

SUBMITTER & SPONSOR: UNITED PHOSPHORUS INC.

TEST MATERIAL: Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

SPECIES: Rat, Wistar

AGE(at dosing): young adult, 9 weeks

WEIGHT (presumably fasted): Males: 204-270 g; Females: 194-235 g

SOURCE: Breeding facility, Jai Research Foundation

EXECUTIVE SUMMARY: *In an acute oral toxicity study (MRID 45654404), fasted (17+ hrs) young adult (9 week old) Wistar rats (5 males and 5 females/dose level) were orally gavaged with Bifenthrin Technical (a white powder containing 99.2% active) in peanut oil at a constant dose volume of 10 mL/kg. Doses in the main study were 0 (vehicle only), 50, 79 and 125 mg/kg.*

At 50 mg/kg 0/5M & 2/5F died; at 79 mg/kg 4/5M & 2/5F died; at 125 mg/kg 5/5M & 3/5F died. All deaths were within 24 hours of dosage. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions in all animals. Survivors were generally normal by Day 3. All survivors had weight gains from Day 0 to Day 7 and again from Day 7 to Day 14, with the exception of one 50 mg/kg female who had the same bodyweight on Day 7 and Day 14.

The rats which died showed findings which included mottling or congestion of the liver and mottling or congestion of the lungs. 13/16 rats found dead had pulmonary congestion, and it is reported that this is a common finding in dead animals with no particular pathological significance. Findings in terminally sacrificed animals were categorized as spontaneous/accidental.

Oral LD50 Males = 66.19 (95% C.L. of 54.48 to 77.90) mg/kg

Oral LD50 Females = 91.89 (95% C.L. of 26.67 to 316.63) mg/kg

Oral LD50 Combined = 74.90 (95% C.L. of 57.29 to 97.92) mg/kg

Bifenthrin technical, a white powder containing 99.2% active ingredient, is in toxicity category II in terms of oral toxicity.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

Procedure (Including deviations from 870.1100): Following preliminary range-finding testing, "four groups of rats, each dose group comprising 5 males and 5 females, were randomly selected and three groups were given a single dose of bifenthrin technical at dose levels of 50, 79 and 125 mg/kg... As the test substance is insoluble in water, it was suspended in peanut oil at the required concentrations prior to dosing. The dose solution was stirred to ensure that there were no visible precipitates. Another group was administered peanut oil at a constant dose volume of 10 mL/kg...as control. A dose volume of 10 mL/kg body weight was calculated for each rat. All animals were dosed once by gavage (day 0) using a metal cannula... Animals were deprived of feed for seventeen hours and fifteen minutes prior to dosing and then three hours after dosing."

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Total
0 (vehicle only)	0/5	0/5	0/10
50	0/5	2/5	2/10
79	4/5	2/5	6/10
125	5/5	3/5	8/10

Observations: All deaths were within 24 hours of dosage. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions in all animals. Survivors were generally normal by Day 3. All survivors had weight gains from Day 0 to Day 7 and again from Day 7 to Day 14, with the exception of one 50 mg/kg female who had the same bodyweight on Day 7 and Day 14.

Gross Necropsy: The rats which died showed findings which included mottling or congestion of the liver and mottling or congestion of the lungs. 13/16 rats found dead had pulmonary congestion, and it is reported that this is a common finding in dead animals with no particular pathological significance. Findings in terminally sacrificed animals were categorized as spontaneous/accidental.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200, formerly §81-2)

Product Manager: 03
MRID No.: 45654405

Reviewer: Byron T. Backus, Ph.D.

CITATION: Tiwari, V.K. Acute Dermal Toxicity Study of Bifenthrin Technical in Rats. JRF Study No. 3416. Unpublished study prepared by Department of Toxicology, Jai Research Foundation, Valvada 396108, Gujarat, India. Final Report Date: FEB-9-2002. MRID 45654405.

SUBMITTER & SPONSOR: UNITED PHOSPHORUS INC.

TEST MATERIAL: Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

SPECIES: Rat, Wistar

AGE(at dosing): not stated; presumably young adult (consistent with body weight data)

WEIGHT: Males: 229-282 g; Females: 216-259 g

SOURCE: Breeding facility, Jai Research Foundation

EXECUTIVE SUMMARY: *In an acute dermal toxicity study (MRID 45654405), groups of 5M & 5F young adult Wistar rats were dermally exposed for 24 hrs (occluded exposure) to either 2000 mg/kg Bifenthrin technical (a white powder with 99.2% purity) mixed with an unspecified amount of peanut oil "to give a slurry," or to 0.2 mL of peanut oil alone.*

There were no mortalities. 9/10 of the rats exposed to bifenthrin showed symptoms (tremors) on Day 3, and two of these rats (both males) also had tremors and piloerection on Days 4-5. All rats were normal from Day 6 through Day 14. All 5 males had bodyweight gains in the period from Day 0 to Day 7, but all 5 females had weight losses during this period; 5/5 males and 4/5 females had bodyweight gains in the period from Day 7 to Day 14.

Necropsy findings (pinpoint lung hemorrhages in one male; bilateral uterine hydrometra in one female) were considered spontaneous and unrelated to exposure to bifenthrin.

The report states that in one preliminary range finding study mortality (in 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg) was observed; this was followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg...and the percent mortality observed was 0, 25 and 25, respectively." This information is considered as 6(a)(2) data, and a detailed report should be submitted to the Agency.

Dermal LD50 Males > 2000 mg/kg (0/5 died at this dose level)

Dermal LD50 Females > 2000 mg/kg (0/5 died at this dose level)

Dermal LD50 Combined > 2000 mg/kg (0/10 died at this dose level)

Bifenthrin technical, a white powder containing 99.2% active, is in toxicity category III in terms of dermal toxicity, based on the dermal LD50 > 2000 mg/kg.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements were provided.

Procedure (including deviations from 870.1200): "A dose range finding study for bifenthrin technical was performed using four (2 male and 2 female) animals per group. The per cent mortality observed were 25, 25 and 50 at the dose levels of 500, 1000 and 2000 mg/kg body weight. Based on above results, main study was conducted at the dose level of 700, 1260 and 2268 mg/kg body weight. As sufficient mortality was not observed at the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg body weight and the per cent mortality observed was 0, 25 and 25, respectively. Therefore, the study was conducted as a limit study using 2000 mg/kg body weight."

"Depending on the result of the range finding study, two groups of rats, comprising 5 males and 5 females per group, were randomly selected...and one group was given dermal application of bifenthrin technical at the dose level of 2000 mg/kg body weight. As bifenthrin technical was insoluble in water, the measured/calculated quantity of bifenthrin technical was mixed with peanut oil, to give a slurry, for even application on the exposed part of the skin. The other group of ten animals (5 male and 5 female), which served as control, was simultaneously treated with 0.2 mL of peanut oil and maintained in similar experimental conditions. The test substance was held in contact with the skin with a porous gauze dressing (not more than 8 ply) and Medi tape 330 hypo-allergic surgical tape...throughout the 24 hour of exposure period to prevent evaporation of the test substance and to ensure that the animals did not ingest it. At the end of the exposure period, the residual test substance was removed using cotton moistened with distilled water."

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
0	0/5	0/5	0/10
2000	0/5	0/5	0/10

Observations: None of the rats showed any clinical signs from Day 0 to Day 2. 5/5 males and 4/5 females had tremors on Day 3; all but 2 males had recovered the following day. The 2 males showed tremors and piloerection on Days 4 and 5, but were normal on Day 6. All 5 males gained weight in the period from Day 0 to Day 7, while all 5 females lost weight during this same period. All males continued to gain weight in the period from Day 7 to Day 14, but one female lost weight during this period and 3 others, although gaining some weight, had still lost a few grams from their initial (Day 0) weight.

Gross Necropsy: 2000 mg/kg: 3/5 males and 4/5 females had NAD (No abnormalities detected). One male had pin-point hemorrhages (mild) of the lungs; the other male had blotched kidneys and a few pin-point hemorrhages of the lungs. One female had partial consolidation in the right cranial lobe of the lung.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D285143
2. PC CODE: 128825 Bifenthrin
3. CURRENT DATE: January 8, 2003
4. TEST MATERIAL: EPA File Symbol 70506-RI; Bifenthrin Technical; (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate; CAS 82657-04-3; purity 99.2%, a white powder

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat/ Jai Research Foundation Gujarat India/Study No. 3415/FEB-9-2002	45654404	LD ₅₀ (M) = 66.2 (54.5-77.9) mg/kg; LD ₅₀ (F) = 91.9 (26.7-316.6)mg/kg; LD ₅₀ (Combined) = 74.9 (57.3-97.9) mg/kg. Dose levels: 50, 79 & 125 mg/kg of test material in peanut oil at a constant dose volume of 10 mL/kg. Symptoms at all dose levels included tremors and nasal discharge; other observations (at 79 mg/kg and above) included abdominal breathing, nasal irritation and piloerection. At 125 mg/kg symptoms also included tonic-clonic convulsions. Survivors were generally normal by Day 3.	II	A
Acute Dermal Toxicity/rat/ Jai Research Foundation Gujarat India/Study No. 3416/FEB-9-2002.	45654405	There were no mortalities among 5M & 5F dermally exposed to 2000 mg/kg. 9/10 rats had tremors on Day 3, and 2 of these (both males) had tremors and piloerection on Days 4-5. All rats were normal Days 0-2, Days 6-15. All 5M had bodyweight gains in the period from Day 0 to Day 7, but all 5F had weight losses; 5/5 males and 4/5 females had bodyweight gains in the period from Day 7 to Day 14. Necropsy findings (pinpoint lung hemorrhages in one male; bilateral uterine hydrometra in one female) were considered spontaneous and unrelated to exposure to bifenthrin. Report states that in a preliminary range finding study 1/4 rats at 500 mg/kg, 1/4 at 1000 mg/kg, and 2/4 at 2000 mg/kg died; followed by a "main study" at 700, 1260 and 2268 mg/kg. "As sufficient mortality was not observed in the main study, the dose range finding study was conducted again using the dose levels of 500, 1000 and 2000 mg/kg... and the percent mortality observed was 0, 25 and 25, respectively."	III	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated

From recent Draft HED risk
assessment for bifenthrin.

ACUTE TOXICITY

Acute Toxicity of Bifenthrin.

Guideline No.	Study Type	MRID #(S)	Results	Toxicity Category
81-1	Acute Oral	00132519	LD ₅₀ = 70.1 mg/kg (♂) LD ₅₀ = 53.8 mg/kg (♀)	II
81-2	Acute Dermal	00132520	LD ₅₀ > 2000 mg/kg	III
81-3	Acute Inhalation	---	no studies	--
81-4	Primary Eye Irritation	00132522	non-irritant	IV
81-5	Primary Skin Irritation	00132521	non-irritant	IV
81-6	Dermal Sensitization	00132523	not a sensitizer	--



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 12 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Product Chemistry Review
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI

EPA has completed its review of product chemistry data submitted in support of this application for registration (MRID#456544-01, 456544-02 and 456544-03). A copy of the review is enclosed for your records. The review identifies a number of deficiencies which must be addressed before this product can be registered. Furthermore, until additional product chemistry information is submitted, we cannot make the determination whether the product is substantially similar to FMC's bifenthrin technical (EPA Reg. No. 279-3055). Please refer to the enclosed review for details regarding the product chemistry data deficiencies.

EPA has not yet completed its review of the acute toxicity data submitted/cited to support registration. We will advise you of the results of our review once it is completed.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,

A handwritten signature in cursive script that reads "Susan L. Stanton, for".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

DP BARCODE: D285142

#14054

CASE: 072204
SUBMISSION: S620915

DATA PACKAGE RECORD
BEAN SHEET

DATE: 08/30/02
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 166 RESB NEW PRO-OC-MIN CHG
RANKING : 10 POINTS ()
CHEMICALS: 128825 Bifenthrin (ANSI)

99.4000%

ID#: 070506-RI BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE

COMPANY: 070506 UNITED PHOSPHORUS INC

PRODUCT MANAGER: 03 ARNOLD LAYNE

703-305-6249 ROOM: CM2 212

PM TEAM REVIEWER: SUSAN STANTON

703-305-5218 ROOM: CM2 237

RECEIVED DATE: 08/30/02 DUE OUT DATE: 02/26/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 285142 EXPEDITE: N DATE SENT: 08/30/02 DATE RET.: / /

CHEMICAL: 128825 Bifenthrin (ANSI)

P TYPE: 001 Submission Related Data Package

CSF: Y

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 12-9-02
01-17-03

DIV : RD

8/30/02

/ /

NEGOT DATE: / /

BRAN: TRB

9/10/

/ /

PROJ DATE: / /

SECT: CHEM

9/10/

/ /

REVR : Kurney

12/6/02

12/10/02

CONTR:

* * * DATA REVIEW INSTRUCTIONS * * *

United Phosphorus, Inc. has submitted an application to register a me-too technical bifenthrin product. In support of the application they have submitted Group A product chemistry data (MRID#456544-01), an accelerated storage stability study (MRID#456544-03) and some Group B data (color, physical state and odor; MRID# 456544-02). For other requirements they are using the cite-all method, based on the product's substantial similarity to FMC's registered technical (EPA Reg. No. 279-3055). Please review the submitted data and determine whether they are acceptable. Also, please determine whether the product is substantially similar to FMC's technical and whether they have submitted or cited adequate data to fulfill the product chemistry requirements for a technical product. A copy of the data matrix listing submitted and cited data is included for your review. I have also attached copies of the CSFs and labels for this new product and FMC's technical for your review. If you have any questions, let me know.

Thanks,
Susan Stanton

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

DP BARCODE: D285142

CASE: 072204
SUBMISSION: S620915

DATA PACKAGE RECORD (CONTINUED)
BEAN SHEET

DATE: 08/30/02
Page 2 of 1

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
285143	TRB/TOX	08/30/02	01/17/03	Y	Y	Y

DATE: December 10, 2002

SUBJECT: Product Chemistry Review of Bifenthrin Technical

FROM: Linda L. Kutney
Product Chemistry Team
Technical Review Branch/RD (7505C)

TO: Arnold Layne, Susan Stanton PM 3
Insecticide Branch/ RD (7505C)

DP BARCODE: D285142
EPA REG. NO.: 70506-RI
REGISTRANT: United Phosphorus, Inc.
USE: Insecticide

Linda L. Kutney
SBR
12-11-02

INTRODUCTION:

United Phosphorus, Inc. has submitted product chemistry data to support the registration of "Bifenthrin Technical. Insecticide/Miticide." The chemical name for Bifenthrin is "(2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate." The proposed basic CSF is dated 2/8/02.

This proposed label is for insecticide/miticide non-food use, including as a termiticide and soil contact nonfumigation treatment, as wood treatment and protection, as outdoor insect control, on ornamental plants, trees, shrubs and woody vines, residential lawns and for indoor insect control., spot or crack and crevice treatment in non-food areas. Use in food or feed areas is prohibited. The product chemistry data has been submitted under MRIDs 456544-01, 456544-02 and 456544-03.

In their letter of 4/8/02, United Phosphorus has also claimed similarity to FMC's Bifenthrin Technical, Reg. No. 279-3055, containing 94.0% of Bifenthrin ai, and a minimum of 97% cis isomers and a maximum of 3% of trans isomers, as listed on the label accepted 6/21/01. No minimum of trans Bifenthrin isomers was included on the approved label.

BARCODE: D285142; Reg. No. 70506-RI PRODUCT: Bifenthrin Tech. Insecticide/Miticide

SUMMARY OF FINDINGS:

1. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160.
2. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162.
3. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167.

BARCODE:D285142;Reg. No. 70506-RI PRODUCT: Bifenthrin Tech.Insecticide/Miticide

CONCLUSION:

The nominal concentration of bifenthrin in Bifenthrin Technical Insecticide/Miticide does not fall within the upper and lower certified limits claimed for FMC's Bifenthrin Technical. Insufficient physical chemical data were submitted to conclude that the proposed technical was substantially similar to FMC's Bifenthrin Technical, Reg. No. 279-3055, from a physical chemistry standpoint.

TRB concludes that the registration request for Bifenthrin Technical Insecticide/Miticide is not acceptable, from a product chemistry standpoint. Deficiencies are numbered below, grouped by type.

CSF deficiencies include:

1. A value must be given for density in block 7, in agreement with the study results.
2. A value must be given for pH in block 8, in agreement with the study results.
3. The "non-applicable" flash point given in block 9 must be supported by study results.
4. The chemical name for bifenthrin must be included in column 10 of the CSF, as required.
5. The minimum listed for the cis isomer in column 10 (for the total bifenthrin), 97%, does not agree with the lower certified limit for the cis isomer given in column 14b.
6. It should be very clear that the minimum and maximums listed in column 10 for cis and trans isomers of bifenthrin correspond to the fractions of the total bifenthrin.

Subgroup A physical chemical data requirements include:

7. product identity and composition (guideline reference 830.1550, 40CFR158.155) The nominal, upper and lower concentrations of bifenthrin in Bifenthrin Technical Insecticide/Miticide listed in the CSF does not agree with the values listed in the study (MRID 456544-01).
8. certified limits (guideline reference 830.1750, 40CFR158.175) See comments included under heading, CSF, above. Note that the certified limits given in the study do not agree with those on the CSF. This must be explained and corrected. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

9. The product chemistry data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) do not satisfy the data requirements of 40CFR§158.170 because they do not support the nominal and upper and lower certified limits on the CSF.

10. Analytical Method (guideline reference 830.1800, 40CFR158.180) The method indicates that cis and trans bifenthrin is separated and quantitated, but the Registrant should give details as to how this is accomplished.

11. Samples must be submitted to the Agency laboratory upon registration of the product (guideline 830.1900, 40CFR158.190).

For full registration, United Phosphorus must submit the following Subgroup B physical chemical studies (See 40CFR Section 190):

STUDY:	GUIDELINE REFERENCE #:
Stability to normal and elevated temperatures, metals, metal ions	830.6313
Oxidation Reduction: chemical incompatibility	830.6314
Flammability	830.6315
Explosibility	830.6316
Storage stability	830.6317
Corrosion Characteristics	830.6320
pH	830.7000
Melting point/range	830.7200
Boiling point/range	830.7220
Density/Relative Density/Bulk Density	830.7300
Dissociation constant in water	830.7370
Partition coefficient (n-oct/water)shake flask method	830.7550
Water Solubility column elution method, shake flask method	830.7840
Solubility in organic solvents	

BARCODE: D285142; **Reg. No.** 70506-RI **PRODUCT:** *Bifenthrin* Tech. Insecticide/Miticide

830.1550. Product Identity:

Common Name: Bifenthrin Technical

Chemical Name: "(2-methyl[1,1'-biphenyl]-3-yl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate."

CAS No.: 82657-04-3 for cis isomer, 83322-02-3 for trans isomer

PC Code No.: 128825 for cis and trans mix

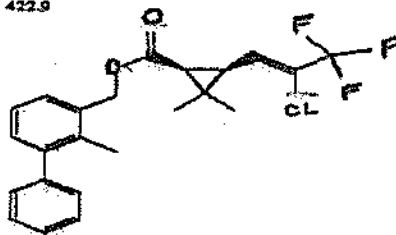
Empirical formula: C₂₃ H₂₂ Cl F₃ O₂

Molecular Weight: 422.9 g/Mole

Structural formula and additional product identity data (from MRID 456544-01)

Trade Name:
Molecular Formula:
Molecular Weight:
Structural Formula:

Bifenthrin Technical.
C₂₃H₂₂ClF₃O₂
422.9



BARCODE:D285142;Reg. No. 70506-RI PRODUCT: Bifenthrin Tech.Insecticide/Miticide

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Table 1: Manufacturing and Impurity Data for United Phosphorus 's Bifenthrin T/TGAI.				
GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product identity and composition	CSF 2/8/02 456544-01	N	Nominal concentrations and certified limits for the AI & all the impurities provided in the CSF do not agree with the study results in MRID 456544-01.
830.1600	Description of materials used to produce product	456544-01	A	The product specification sheets (MSDS) for the starting materials were submitted.
830.1650	Description of production process	456544-01	A	The registrant provided detailed information about the synthesis of the technical. Amounts of each starting material and the conditions of the reaction were provided.
830.1670	Discussion of formation of impurities	456544-01	A	The registrant provided the required information on the formation of impurities.
830.1700	Preliminary analysis	456544-01	A	Method validation indicates that the method is adequate for the determination of the ai. Analysis was conducted on 5 production batches of the ai.
830.1750	Certified limits	2/8/02 CSF	N	The certified limits given in the CSF are not in agreement with the study.

Table 1: Manufacturing and Impurity Data for United Phosphorus 's Bifenthrin T/TGAI.

GLN	Requirement	MRID	Status	Details and/or Deficiency
830. 1800	Enforcement analytical method	456544-01	A	<p>"HPLC Method for Determination of Bifenthrin" Compilation Report UPI-Bifentec-A., dated 3/19/02.</p> <p>Bifenthrin test sample is dissolved in HPLC grade acetonitrile, and an aliquot is subjected to reverse phase LC. The cis and trans isomers are combined in a single LC peak and then separate quantitation accomplished using UV detection at 254 nm, using external standard quantitation. <i>The method should explain how cis and trans bifenthrin is separated and quantitated.</i></p>
830. 1900	Submission of Samples	456544-01	A	<p><i>Samples must be provided prior to registration.</i></p>
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.				

BARCODE:D285142;Reg. No. 70506-RI PRODUCT: *Bifenthrin* Tech.Insecticide/Miticide

Table 2: Physical and Chemical Properties for the <i>BIFENTHRIN</i> technical .				
GLN	Requirement	MRID	Stat-us ¹	Result or Deficiency
830.6302	Color	456544-02	A	White
830.6303	Physical state	456544-02	A	Solid Powder
830.6304	Odor	456544-02	A	None
830.6313	Stability to normal & elevated temperatures, metals, and metal ions.		N	
830.6314	Oxidation Reduction: chemical incompatibility		N	
830.6315	Flammability		N	
830.6316	Explosability		N	
830.6317	Storage stability	456544-03	N	<i>No significant change noted after storage at 54 ± 2 C for 14 days.</i> <i>Stability Testing at 3, 6, 9, 12, 18, and 24 months is required for full registration.</i>
830.6319	Miscibility		NA	Not a liquid at 20 C.
830.6320	Corrosion characteristics	456544-03	N	<i>No significant change was noted after storage at 54 ± 2 C for 14 days.</i> <i>Corrosion Characteristics Testing at 3, 6, 9, 12, 18, and 24 months is required for full registration.</i>

Table 2: Physical and Chemical Properties for the *BIFENTHRIN* technical .

GLN	Requirement	MRID	Status ¹	Result or Deficiency
830.6321	Dielectric Breakdown Voltage		NA	Not Required. Not used around electrical equipment.
830.7000	pH		N	
830.7050	UV/Visible absorption		NA	Not a liquid at 20 C.
830.7100	Viscosity		NA	Not a liquid at 20 C.
830.7200	Melting point/range		N	
830.7220	Boiling point/range		N	
830.7300	Density/relative density/ bulk density		N	
830.7370	Dissociation constant in water		N	
830.7550	Partition coefficient (n-octanol/water) shake flask method		N	
830.7840	Water solubility: column elution method; shake flask method Solubility in organic solvents		N	
830.7950	Vapor pressure		NA	Not a liquid at 20 C
¹ A = Acceptable; N = Not Acceptable (see Deficiency); NA = Not applicable.				
² For example, "brown" for 830.6302; "155° C" for 830.7200.				

Pages 188-192-*Privileged attorney-client communication*

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September 12, 2002

VIA FACSIMILE

Freedom of Information Act Officer
Freedom of Information Office (1105)
U.S. Environmental Protection Agency
1300 Pennsylvania Ave., N.W.
Washington, D.C. 20460
Tel: (202) 566-1667
Fax: (202) 566-2147

* OGC

* DECA CPPTS

HQ-RIN-02509-02

Due: 10/1/02

10/1/02
1:58

Re: Freedom of Information Request

Dear Sir or Madam:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, and the implementing regulations of the Environmental Protection Agency ("EPA"), 40 C.F.R. § 2.100 *et seq.*, I hereby request all correspondence and other documentation related to compliance of United Phosphorous, Inc., with 40 C.F.R. Section 152, subpart E requirements for its application for registration of bifenthrin technical. These documents include, but are not limited to, EPA's April 25, 2002 letter referenced in the attached letter dated June 3, 2002. I also request any documents from EPA's Office of General Counsel, or any other office, regarding EPA's position on the timing of submission of offers to pay compensation and/or certifications with respect to citation of data.

I am not requesting any confidential business information ("CBI"). If any of the documents responsive to this request contain CBI, please supply the documents with CBI redacted.

We agree to any necessary and reasonable charges, which would not exceed \$250.00, for obtaining this information; otherwise, please notify me by telephone at (202) 637-1025.

When the information is available, please call me so I can make arrangements for pick-up or fax it to me at (202) 637-2201. Thank you in advance for your assistance.

Respectfully submitted,



C. Felix Amerasinghe
of LATHAM & WATKINS

Attachments

Commercial

Frances Mann
305-7449



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 3 2002

OFFICE OF
PREVENTION PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI
Your Resubmission Dated May 8, 2002

EPA has reconsidered its position with respect to the subject application and determined that the application is incomplete for the reasons given in the Agency's April 25, 2002 letter:

"An application is considered incomplete if any pertinent item specified in §152.50 has not been submitted. Pursuant to §152.50(f) an applicant must submit materials to demonstrate that he has complied with FIFRA sec. 3(c)(1)(D) and subpart E of part 152 (Procedures to Ensure Protection of Data Submitters' Rights). Therefore, you must submit a completed Certification with Respect to Citation of Data (EPA Form 8570-34) indicating the Method of Data Support you are using. You must also submit a list of companies sent offers of compensation for data you are citing in support of this application."

We reached our decision after consultation with attorneys in the Office of General Council and the Registration Division's senior management team. It was agreed that applications which do not comply with the data compensation regulations at the time of submission will be considered incomplete and that we will not spend resources reviewing such applications until materials to complete the application have been submitted. We recognize that you may have been allowed in the past to submit these materials later in the review process. However, we do not believe that this practice is supported by the regulations. The regulation which you cite as allowing submission at a later point (40 CFR §152.84) has been interpreted to mean that the Agency would not reject an application outright if it is missing information on the data compensation forms. The regulation does not envision that an applicant be required to comply with subpart E only after the application has been determined to be acceptable for registration. Such a determination cannot be made until the data compensation requirements have been met.

-2-

Your May 8, 2002 letter asked us to confirm that the subject application has been determined to be acceptable. It has not. We have not begun to review the data, data matrix, CS or draft label which you submitted in support of registration and will not begin review of these materials until you submit the information requested above.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,



George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)



1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

5620 9/15
H. LaRocca
COPY

DIRECT: 703-492-7905
MAIN: 703-492-0445
Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

August 29, 2002

Document Processing Desk
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: George LaRocca (PM 13)

Re: Application for Registration of Bifenthrin Technical Insecticide/Miticide,
United Phosphorus, Inc. EPA File Symbol 70506-RI
Agency Letters of April 25, 2002 and August 14, 2002

Dear George:

On behalf of our client, United Phosphorus Inc., enclosed please find EPA Form 8570-34, Certification with Respect to Citation of Data. United Phosphorus has made the appropriate offers to pay compensation.

This form is being submitted at this time in order to avoid any further delays in the Agency's review of this application (filed April 11, 2002) while the continuing issues associated with the revised interpretation of the timing of this certification in relation to Agency review of applications for registration is still being resolved. While we were reassured in the Agency letter of August 14, 2002, that the above application was not being treated as withdrawn pending resolution of the issues, there has been and will be no progress in the Agency's review of the application pending such resolution or submission of the appropriate certification. United Phosphorus will suffer economic hardship if there are significant delays in resolving the issues.

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ChemReg

INTERNATIONAL, LLC

Letter to G. LaRocca, US EPA, August 29, 2002, page 2

We still believe that as expressly permitted under 40 CFR 152.84 and EPA's Federal Register notice regarding that regulation (40 Fed. Reg. 30884, Aug 1, 1984), United Phosphorus is allowed to submit a completed Certification with Respect to Citation of Data form to your office, and send the necessary data compensation offers to companies listed on the data matrix, *at any time before registration is approved*. We believe that 40 FR 30884 is correct in identifying that the Agency will not delay the review of the application pending receipt of these statements, but will not approve the application until they are received and determined to be in compliance.

With this submission, we request that the Agency begin review of application for registration submitted on April 11, 2002 by United Phosphorus, Inc. for Bifenthrin Technical Insecticide/Miticide (EPA File Symbol 70506-RD). It is our understanding that the appropriate discussions should and will continue regarding the issues of the timing of submission of such certifications for future applications.


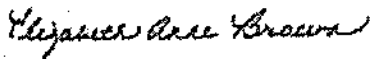
Please let me know if you have any questions.

Regards,

Elizabeth Anne Brown

Elizabeth Anne Brown

cc: United Phosphorus, Inc.
Telisport Putsavage, Esq., Wright & Sielaty, P.C.

		United States Environmental Protection Agency Washington, DC 20460		Registration Amendment <input checked="" type="checkbox"/> Other		OPP Identifier Number	
Application for Pesticide - Section I							
1. Company/Product Number 70506-RI		2. EPA Product Manager George LaRocca		3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted			
4. Company/Product (Name) Bifenilrin Technical Insecticide/Miticide		PM # 33					
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____					
<input type="checkbox"/> Check if this is a new address							
Section - II							
<input type="checkbox"/> Amendment - Explain below		<input type="checkbox"/> Final printed labels in response to					
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> Agency letter dated <input type="checkbox"/> "Me Too" Application					
<input type="checkbox"/> Notification - Explain below		<input checked="" type="checkbox"/> Other - Explain below					
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Submission of Form 8750-34							
Section III							
1. Material This Product Will be Packaged In:							
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
*Certification must be submitted		If "Yes" Unit Packaging wgt.		No. per container		If "Yes" Package wgt	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of label directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product			
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			
Section IV							
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)							
Name Elizabeth Anne Brown		Title ChemReg International, LLC Authorized agent		Telephone No. (include Area Code) 703-492-7905			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.						6. Date Application Received (Stamped)	
2. Signature 		3. Title ChemReg International, LLC Authorized Agent					
4. Typed Name Elizabeth Anne Brown		5. Date August 29, 2002					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

United Phosphorus, Inc.
 423 Riverview Plaza
 Trenton, NJ 08611
 609-392-8200

EPA Registration Number/File Symbol

70506-R1

Active Ingredient(s) and/or representative test compound(s)

bifenthrin

Date

August 29, 2002

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 155)

Terrestrial Non-Food, Domestic Outdoor, Indoor

Product Name

Bifenthrin Technical Insecticide/Miticide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature

Ann M. Tillman

Date

August 29, 2002

Typed or Printed Name and Title

Ann M. Tillman
 Technical Director



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 14 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI

In EPA's April 25, 2002 letter to you regarding the subject application, the Agency indicated that the application would be considered administratively withdrawn if the listed deficiencies were not corrected within 75 days. On June 3, 2002, in response to your submission of May 8, 2002, the Agency reiterated that it would not further review the above referenced application until the identified deficiencies had been corrected, but EPA did not at that time indicate that a new 75-day "clock" would commence following the June 3rd letter.

The Agency is in receipt of a June 27, 2002 letter on your behalf from Telisport Putsavage, Esq. with regard to those deficiencies. It is my understanding that Mr. Putsavage has also spoken with EPA General Counsel staff requesting that UPI's application not be treated as withdrawn pending the resolution of the concerns outlined in the June 27 letter and by other parties regarding EPA review of incomplete applications. By this letter, I wish to confirm that EPA will not treat the referenced application as withdrawn pending resolution of these matters.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,

A handwritten signature in black ink, appearing to read "G. LaRocca".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

July 26, 2002

Patricia A. Roberts, Esq.
Associate General Counsel for Pesticides and Toxics
U.S. Environmental Protection Agency
Office of General Counsel
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Offers to Pay for Follow-on Registrants

Dear Ms. Roberts:

On behalf of the Chemical Producers and Distributors Association (CPDA), I am writing to you concerning EPA's long-standing policy of allowing "me-too" or generic registrants to submit a Certification with Respect to Citation of Data (EPA Form 8570-34) "at any later time prior to EPA's approval of the application." 40 CFR §152.84

By way of background, CPDA is a voluntary, non-profit organization of about 90 companies engaged in the formulation, manufacture, distribution, and sale of some \$6 billion worth of generic products used on food, feed, and fiber crops and in the care of lawns, gardens and turf. Many of our members are involved in the development and sale of adjuvants and inerts used to increase the efficacy of crop protection formulations as well as a variety of copper-based pesticide products. As such, EPA rules, regulations, and guidelines affect our member companies significantly.

For the past eighteen years and until very recently, Agency practice has been clear, and interpretation of the applicable regulations has been consistent.

The Agency promulgated the final rule entitled Procedures to Ensure Protection of Data Submitters' Rights, 40 CFR §152.80 et seq., on August 1, 1984. See 49 Fed. Reg. 30,884. That rule took effect on April 25, 1985. See 50 Fed. Reg. 16234.

Section 40 CFR §152.84 states:

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable. (emphasis added)

In addition, the Preamble to the August 1, 1984 publication entitled Agency Review to Determine Compliance clearly discusses in Section VII the Agency's interpretation of its policy, and specifically clarifies both the timing of an applicant's

registration and the timing of the submission of a Certification with Respect to Citation of Data.

The Preamble unequivocally states:

Under FIFRA section 3(c)(5)(B), the Agency must review applications to determine whether the materials required to be submitted, including those that are required by this Subpart E, comply with the requirements of the Act. This part of the review need not take place before the Agency begins to review the application for compliance with other statutory requirements, but must occur before the registration is approved. EPA recognizes that the correspondence requirements of this subpart may take some time, and that an applicant may not wish to await responses in all cases before filing his application. A notable example is data gap certifications: if a data gap is suspected, the applicant can not claim that the gap exists until he has waited 60 days after corresponding with data submitters. EPA sees no reason why correspondence times and Agency review times may not run concurrently. Section 152.84 therefore provides that applicants may submit materials required by this subpart at any time before registration is granted. The Agency will not delay the review of other information pertinent to the application pending receipt of lists and certification statements, but will not approve the registration until they are received.

Applicants should be aware, however, that if deficiencies are found in materials submitted late in the Agency's review, the registration could be delayed while the applicant corrects the problem. If the Agency completes its review of the application, but has not received the applicant's submissions under this rule, the Agency will send the applicant a rejection letter, which will include a 75-day response time, after which the application will be treated as though it had been withdrawn. A new application will be required if the applicant wants to pursue registration at some later date. 49 Fed. Reg. 30884, at 30897. (emphasis added)

Despite the clearly-worded Preamble and EPA's own regulations, it appears that the Agency is reconsidering its policy of the last eighteen years. We at CPDA strongly urge the Agency to retain its long-standing interpretation of its regulation. The implications of a potential policy shift are enormous.

First, rather than expediting the registration process and using fewer Agency resources, the policy change would slow down the registration process, encourage delays and additional review, delay entry of generic products to the marketplace and decrease competition. Such a shift would result in severe, direct negative economic impacts on farmers, ranchers, consumers, and pesticide consumers.

Second, by requiring "me-too" registrants to make data compensation offers to pay prior to processing of pesticide applications, the "extra" eighty-to-ninety days will

give the original data submitter additional time to file petitions to deny such registrations and provide more lead time to file a petition to cancel once EPA has approved the products. The proposed policy change will create an incentive for frivolous petitions to deny, designed to stall the process. In the meantime, Agency staff time will be diverted to process the petitions.

Third, rather than saving EPA resources, more staff time and resources will be required while the approval process for "me-too" or generic products will be slowed down.

Fourth, if EPA insists on this new interpretation of Section 40 CFR §152.84, the Agency will experience an onslaught of petitions to cancel registrations previously granted under the "old" interpretation of the regulations. These challenges to existing regulations could be based upon untimely offers to pay. These appeals would also consume more EPA time and resources.

Fifth, the language in the regulation – "at any later time" is unambiguous. If one argues that the offer to pay must be submitted with the application, it would completely undermine the clear language and intent of the regulation.

If the Agency is considering a change to the language of 40 CFR § 152.84, the Agency should comply with the Federal Administrative Procedures Act (5 U.S.C. §551) by giving public notice and seeking public comment. All affected parties should have an opportunity to review and comment on a proposed change to the regulation.

We at CPDA urge the Agency to retain its long-standing interpretation of 40 CFR §152.84, and dismiss other EPA efforts to undermine and alter the clear intent of the regulations.

Moreover, we at CPDA strongly support the letter from Telisport W. Putsavage of Wright & Sielaty, P.C., to you dated June 27, 2002 concerning this same matter.

As this issue affects hundreds of generic registrants, we request a meeting to discuss this important issue.

Very truly yours,

Warren E. Stickle, PhD.
President

cc: Marcia Mulkey
Jim Jones
Debbie Edwards
George LaRocca

Michelle Knorr

WRIGHT & SIELATY, P.C.

COUNSELORS AT LAW

1990 OLD BRIDGE ROAD, SUITE 202

LAKE RIDGE, VIRGINIA 22192-2383

TELISPORT W. PUTSAVAGE

DIRECT: 703-492-0788

E-MAIL: putsavage@chemlaw.com

PHONE: 703-492-0055

FAX: 703-492-0066

WEB: www.chemlaw.com

FAX MESSAGE

DATE: July 23, 2002

TO: George Larocca

FAX: 703-605-1225

PHONE: 703-305-6100

PAGES: 8 (Including Cover)

MESSAGE:

THIS WILL BE THE ONLY FORM OF DELIVERY OF THIS DOCUMENT

OFFICES NEAR WASHINGTON, D.C., AND IN ALBANY, NEW YORK

WRIGHT & SIELATY

COUNSELORS AT LAW

1990 OLD BRIDGE ROAD
LAKE RIDGE, VIRGINIA 22192-3026

703.492.0738
FACSIMILE 703.492.0066
putsavage@chemlaw.com

TELISPORT W. PUTSAVAGE

ADMITTED IN NEW YORK AND MARYLAND
NOT ADMITTED IN VIRGINIA

Also at
One Steuben Place, Suite 5
Albany, New York 12207

July 23, 2002

By Facsimile and Overnight Mail

Patricia A. Roberts, Esq.
Associate General Counsel for Pesticides and Toxics
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Application for Registration of Bifenthrin Technical Insecticide/Miticide
United Phosphorus, Inc., EPA File Symbol 70506-RI

Dear Ms. Roberts:

I write to you in further regard to the timing of offers to pay data compensation that I raised in my letter to you of June 27, 2002. That letter addressed the issue raised in a letter of June 3, 2002 from Mr. George LaRocca, Product Manager 13 in the Insecticide Branch of the Registration Division in the Office of Pesticide Products, to Dr. Elizabeth Brown of ChemReg International as agent for United Phosphorous, Inc. ("UPI"). I had requested that the Agency rescind the notice of June 3, 2002 from Mr. LaRocca and continue to process the application in question, or in the absence of a rescission, that you advise me in writing of that fact and whether such refusal is final agency action on this matter. To date I have received no response to my letter or my telephone follow-up.

I suggest that if the Agency requires further time to review its position on this subject that it nonetheless proceed to process the referenced application for registration. Since the policy in question at the least has not been uniformly applied, and given the widespread lack of industry awareness of the policy, it would seem equitable that the policy be applied to new applications following an announcement to regulated community of the Agency's position. Under this approach, the application in question could continue to be processed.

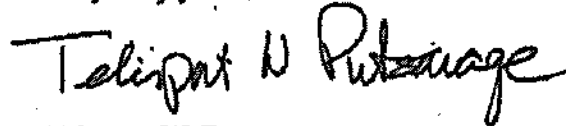
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OFFICES NEAR WASHINGTON, D.C., AND IN ALBANY, NEW YORK

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq
July 23, 2002
Page 2 of 2

If we are unable to be assured that our client's rights are being protected in the current circumstances, our client will be forced to consider what avenues of legal recourse are available. It would be an unfortunate waste of the resources of both our client and the Agency if we were forced to pursue other options simply to preserve the status quo in the absence of a response from the Agency.

Very truly yours,



Tellsport W. Putsavage

cc: Ms. Marcia Mulkey, Director, Office of Pesticide Products
Ms. Debbie Edwards, Acting Director, Registration Division
Ms. Deborah McCall, Insecticide Branch, Registration Division
Mr. George LaRocca, Product Manager, Insecticide Branch
Michelle Knorr, Esq., Pesticides and Toxic Substances Law Office
Mr. Jeffrey S. Pritchard, United Phosphorus Inc.

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TELISPORT W. PUTSAVAGE

ADMITTED IN NEW YORK AND MARYLAND
NOT ADMITTED IN VIRGINIA

Also at
One Steuben Place, Suite 5
Albany, New York 12207

June 27, 2002

By Facsimile and Overnight Mail

Patricia A. Roberts, Esq.
Associate General Counsel for Pesticides and Toxics
U.S. Environmental Protection Agency
Office of General Counsel
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Application for Registration of Bifenthrin Technical Insecticide/Miticide,
United Phosphorus, Inc., EPA File Symbol 70506-RI

Dear Ms. Roberts:

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In his June 3, 2002 letter Mr. LaRocca states that the application referenced above is incomplete and will not be processed because a Certification with Respect to Citation of Data (EPA Form 8570-34) was not included with the application. However, in submitting this application on April 8, 2002, Dr. Brown had requested that she be notified upon completion of the review of application, at which time the Certification would be submitted. This practice, which Mr. LaRocca states that he is now refusing to follow, accords with past Agency practice and the applicable regulations.

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WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 2 of 5

Mr. LaRocca states that upon advice of the Office of General Counsel and senior management in the Office of Pesticide Programs:

The regulation which you cite as allowing submission at a later point (40 CFR §152.84) has been interpreted to mean that the Agency would not reject an application outright if it is missing information on the data compensation forms. The regulation does not envision that an applicant comply with subpart E [40 CFR §152.80 et seq.] only after the application has been determined to be acceptable for registration. Such a determination cannot be made until the data compensation requirements have been met. (emphasis in the original)

This position represents a major change in the Agency's approach and interpretation of regulations applicable to the processing of registration applications citing the data of other registrants. We believe that this change has been implemented in violation of the Federal Administrative Procedure Act, 5 U.S.C. §551 et seq., in that it represents a change to an existing rule that was made without benefit of public notice and comment.

The Agency promulgated the final rule entitled Procedures to Ensure Protection of Data Submitters' Rights, 40 CFR §152.80 et seq., on August 1, 1984. See 49 Fed. Register 30,884. That rule took effect on April 25, 1985. See 50 Fed. Reg. 16234.

Section 40 C.F.R. §152.84 states:

All information required by this subpart should be submitted with the application, but may be submitted at any later time prior to EPA's approval of the application. The Agency will not approve any application until it determines either that the application is not subject to these requirements or that all required materials have been submitted and are acceptable. (emphasis added).

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 3 of 5

In our discussion of this matter, Ms. Knorr argued that the Agency is free to interpret the phrase "at any later time prior to EPA's approval of the application" to mean at the time the application is filed, and that despite our experience to the contrary, has consistently done so. This position directly contradicts both the express text of 40 C.F.R. §152.84 and the Agency's historic interpretation of the rule.

To argue that the phrase "at any later time" can be applied to mean that the certification must accompany the application renders the permissive phrase "should be submitted with the application" meaningless. This position not only defies standard regulatory interpretation principles, but expressly contravenes the position taken by the Agency in promulgating the rule in question. In Section VII of the Preamble of the August 1, 1984 publication, entitled Agency Review to Determine Compliance, the Agency spelled out its approach to the timing of an applicant's registration application in relation to the submission of a Certification with Respect to Citation of Data. The Preamble states:

Under FIFRA section 3(c)(5)(B), the Agency must review applications to determine whether the materials required to be submitted, including those that are required by this Subpart E, comply with the requirements of the Act. This part of the review need not take place before the Agency begins to review the application for compliance with other statutory requirements, but must occur before the registration is approved. EPA recognizes that the correspondence requirements of this subpart may take some time, and that an applicant may not wish to await responses in all cases before filing his application. A notable example is data gap certifications: if a data gap is suspected, the applicant can not claim that the gap exists until he has waited 60 days after corresponding with data submitters. EPA sees no reason why correspondence times and Agency review times may not run concurrently. Section 152.84 therefore provides that applicants may submit materials required by this subpart at any time before registration is granted. The Agency will not delay the review of other information pertinent to the application pending receipt of lists and certification statements, but will not approve the registration until they are received.

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 4 of 5

Applicants should be aware, however, that if deficiencies are found in materials submitted late in the Agency's review, the registration could be delayed while the applicant corrects the problem. If the agency completes its review of the application, but has not received the applicant's submissions under this rule, the Agency will send the applicant a rejection letter, which will include a 75-day response time, after which the application will be treated as though it had been withdrawn. A new application will be required if the applicant wants to pursue registration at some later date. 49 Fed. Register 30884, at 30897. (emphasis added)

Given the express term of the rule and EPA's formally-expressed interpretation of it, the implementation of the contrary position expressed by Mr. LaRocca and Ms. Knorr would require promulgation of an amendment of the rule pursuant to the procedures of the Administrative Procedure Act.

The Agency's position is not only in contravention of the rule but ill-advised on a policy basis. By requiring data-citers to make offers to pay prior to the processing of the application, the Agency will invite numerous petitions to cancel while such applications are being processed, thereby burdening both the Agency and applicants with additional delays in processing applications. In addition, if the Agency insists upon pursuing its new interpretation, counsel for several data submitters have already informed us that they would pursue challenges to existing registrations for which offers to pay were made after the Agency had completed applications reviews. These attacks would be premised upon arguments that the Agency granted registrations without complete applications and based upon untimely offers to pay.

I request that the Agency rescind the notice of June 3, 2002 from Mr. LaRocca and continue to process the application in question. Upon completion of the review, UPI will provide the necessary certification confirming that an offer to pay the data submitter(s) has been made.

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 5 of 5

If the Agency refuses to rescind the June 3rd notice, please immediately advise me in writing of that fact and whether such refusal is final agency action on this matter. In such circumstances, UPI reserves the right to seek an injunction in federal court to compel EPA to comply with the procedural requirements set forth in the 1984 Federal Register.

Very truly yours,



Telisport W. Putsavage

cc: Ms. Marcia Mulkey, Director, Office of Pesticide Products
Ms. Debbie Edwards, Acting Director, Registration Division
Ms. Deborah McCall, Insecticide Branch, Registration Division
Mr. George LaRocca, Product Manager, Insecticide Branch
Michelle Knorr, Esq., Pesticides and Toxic Substances Law Office
Jeffrey S. Fritchard, United Phosphorus Inc.

George LaRocca
7.11.02

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June 27, 2002

By Facsimile and Overnight Mail

Patricia A. Roberts, Esq.
Associate General Counsel for Pesticides and Toxics
U.S. Environmental Protection Agency
Office of General Counsel
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Application for Registration of Bifenthrin Technical Insecticide/Miticide,
United Phosphorus, Inc., EPA File Symbol 70506-RI

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In his June 3, 2002 letter Mr. LaRocca states that the application referenced above is incomplete and will not be processed because a Certification with Respect to Citation of Data (EPA Form 8570-34) was not included with the application. However, in submitting this application on April 8, 2002, Dr. Brown had requested that she be notified upon completion of the review of application, at which time the Certification would be submitted. This practice, which Mr. LaRocca states that he is now refusing to follow, accords with past Agency practice and the applicable regulations.

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 2 of 5

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This position represents a major change in the Agency's approach and interpretation of regulations applicable to the processing of registration applications citing the data of other registrants. We believe that this change has been implemented in violation of the Federal Administrative Procedure Act, 5 U.S.C. §551 et seq., in that it represents a change to an existing rule that was made without benefit of public notice and comment.

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WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 3 of 5

In our discussion of this matter, Ms. Knorr argued that the Agency is free to interpret the phrase "at any later time prior to EPA's approval of the application" to mean at the time the application is filed, and that despite our experience to the contrary, has consistently done so. This position directly contradicts both the express text of 40 C.F.R. §152.84 and the Agency's historic interpretation of the rule.

To argue that the phrase "at any later time" can be applied to mean that the certification must accompany the application renders the permissive phrase "should be submitted with the application" meaningless. This position not only defies standard regulatory interpretation principles, but expressly contravenes the position taken by the Agency in promulgating the rule in question. In Section VII of the Preamble of the August 1, 1984 publication, entitled Agency Review to Determine Compliance, the Agency spelled out its approach to the timing of an applicant's registration application in relation to the submission of a Certification with Respect to Citation of Data. The Preamble states:

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WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 4 of 5

Applicants should be aware, however, that if deficiencies are found in materials submitted late in the Agency's review, the registration could be delayed while the applicant corrects the problem. If the agency completes its review of the application, but has not received the applicant's submissions under this rule, the Agency will send the applicant a rejection letter, which will include a 75-day response time, after which the application will be treated as though it had been withdrawn. A new application will be required if the applicant wants to pursue registration at some later date. 49 Fed. Register 30884, at 30897. (emphasis added)

Given the express term of the rule and EPA's formally-expressed interpretation of it, the implementation of the contrary position expressed by Mr. LaRocca and Ms. Knorr would require promulgation of an amendment of the rule pursuant to the procedures of the Administrative Procedure Act.

The Agency's position is not only in contravention of the rule but ill-advised on a policy basis. By requiring data-citers to make offers to pay prior to the processing of the application, the Agency will invite numerous petitions to cancel while such applications are being processed, thereby burdening both the Agency and applicants with additional delays in processing applications. In addition, if the Agency insists upon pursuing its new interpretation, counsel for several data submitters have already informed us that they would pursue challenges to existing registrations for which offers to pay were made after the Agency had completed applications reviews. These attacks would be premised upon arguments that the Agency granted registrations without complete applications and based upon untimely offers to pay.

I request that the Agency rescind the notice of June 3, 2002 from Mr. LaRocca and continue to process the application in question. Upon completion of the review, UPI will provide the necessary certification confirming that an offer to pay the data submitter(s) has been made.

WRIGHT & SIELATY, P.C.

Patricia A. Roberts, Esq

June 27, 2002

Page 5 of 5

If the Agency refuses to rescind the June 3rd notice, please immediately advise me in writing of that fact and whether such refusal is final agency action on this matter. In such circumstances, UPI reserves the right to seek an injunction in federal court to compel EPA to comply with the procedural requirements set forth in the 1984 Federal Register.

Very truly yours,



Telisport W. Putsavage

cc: Ms. Marcia Mulkey, Director, Office of Pesticide Products
Ms. Debbie Edwards, Acting Director, Registration Division
Ms. Deborah McCall, Insecticide Branch, Registration Division
Mr. George LaRocca, Product Manager, Insecticide Branch
Michelle Knorr, Esq., Pesticides and Toxic Substances Law Office
Jeffrey S. Pritchard, United Phosphorus Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 3 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI
Your Resubmission Dated May 8, 2002

EPA has reconsidered its position with respect to the subject application and determined that the application is incomplete for the reasons given in the Agency's April 25, 2002 letter:

"An application is considered incomplete if any pertinent item specified in §152.50 has not been submitted. Pursuant to §152.50(f) an applicant must submit materials to demonstrate that he has complied with FIFRA sec. 3(c)(1)(D) and subpart E of part 152 (Procedures to Ensure Protection of Data Submitters' Rights). Therefore, you must submit a completed Certification with Respect to Citation of Data (EPA Form 8570-34) indicating the Method of Data Support you are using. You must also submit a list of companies sent offers of compensation for data you are citing in support of this application."

We reached our decision after consultation with attorneys in the Office of General Council and the Registration Division's senior management team. It was agreed that applications which do not comply with the data compensation regulations at the time of submission will be considered incomplete and that we will not spend resources reviewing such applications until materials to complete the application have been submitted. We recognize that you may have been allowed in the past to submit these materials later in the review process. However, we do not believe that this practice is supported by the regulations. The regulation which you cite as allowing submission at a later point (40 CFR §152.84) has been interpreted to mean that the Agency would not reject an application outright if it is missing information on the data compensation forms. The regulation does not envision that an applicant be required to comply with subpart E only after the application has been determined to be acceptable for registration. Such a determination cannot be made until the data compensation requirements have been met.

Your May 8, 2002 letter asked us to confirm that the subject application has been determined to be acceptable. It has not. We have not begun to review the data, data matrix, CSF or draft label which you submitted in support of registration and will not begin review of these materials until you submit the information requested above.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,



George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)



1990 OLD BRIDGE ROAD, SUITE 201
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905
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Fax: 703-492-0668

E-MAIL: brown@chemreg.com
WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

May 8, 2002

Document Processing Desk
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: George LaRocca (PM 13)

Re: Application for Registration of Bifenthrin Technical Insecticide/Miticide,
United Phosphorus, Inc. EPA File Symbol 70506-RI
Agency Letter of April 25, 2002

Dear George:

In your letter of April 25, 2002 (copy enclosed), you stated that the Agency will not continue processing the application for registration of the above product if EPA Form 8570-34 and associated materials were not submitted within 75 days of the date of receipt of your letter. As clearly stated in the submission materials accompanying the application and as expressly permitted under 40 CFR 152.84 and EPA's Federal Register notice regarding that regulation (40 Fed. Reg. 30884, Aug 1, 1984), United Phosphorus is allowed to and will submit a completed Certification with Respect to Citation of Data form to your office, and send the necessary data compensation offers to companies listed on the enclosed data matrix, once we obtain confirmation from your office that the enclosed data matrix is acceptable and that EPA has decided to approve the enclosed application. (See enclosed copy of April 11, 2002 letter).

Your letter of April 25, 2002, is unclear as to whether the Agency has reached a decision on approval of the application for registration. Please confirm in writing that your letter of April 25, 2002, was confirmation that the April 11, 2002 application has been determined to be acceptable and that the Agency has decided to approve the application for registration. Once we receive that confirmation, the appropriate materials will be submitted to the Agency. Until that confirmation is received, however, the applicant is not required to submit the materials requested in your letter and the Agency may not delay review of the application.

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ChemReg

INTERNATIONAL, LLC

George LaRocca
May 8, 2002, page 2

I look forward to your response. Please do not hesitate to contact me if you have any questions.

Regards,



Elizabeth Anne Brown

Enclosures:

1. EPA letter of April 25, 2002 (George LaRocca)
2. ChemReg International, LLC letter of April 11, 2002, on behalf of United Phosphorus

cc: United Phosphorus, Inc.
James Wright, Esq., Wright & Sielaty P.C.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 25 2002

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

RECEIVED
MAY 01 2002

BY:

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI
Your Submission Dated April 11, 2002

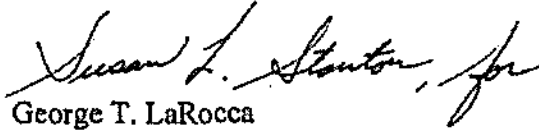
The application referred to above has been determined pursuant to 40 CFR §152.104, not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling, data and/or other information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days, you must notify the Agency within those 75 days of the date you expect to complete the application. If, after 75 days you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new application.

1. An application is considered incomplete if any pertinent item specified in §152.50 has not been submitted. Pursuant to §152.50(f) an applicant must submit materials to demonstrate that he has complied with FIFRA sec. 3(c)(1)(D) and subpart E of part 152 (Procedures to Ensure Protection of Data Submitters' Rights). Therefore, you must submit a completed Certification with Respect to Citation of Data (EPA Form 8570-34) indicating the Method of Data Support you are using. You must also submit a list of companies sent offers of compensation for data you are citing in support of this application.

-2-

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Susan L. Stanton, for".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)



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www.pesticide.net

ELIZABETH A. BROWN, PH.D.

April 8, 2002

Document Processing Desk (APPL)
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: George LaRocca (PM 13)

Re: Application for Registration of "Me-Too" Bifenthrin Technical Insecticide/Miticide

On behalf of our client, United Phosphorus, Inc. (UPI), we are submitting an application for a "me-too" registration of Bifenthrin Technical Insecticide/Miticide (EPA Product Code 128825). This product is substantially similar to the already registered EPA Reg No. 279-3055.

Enclosed please find:

Transmittal bibliography

Three (3) copies of each submitted study

Application form 8570-1

Five (5) copies of the proposed label

Data matrix forms for EPA and public use (Form 8570-35)

Please note that we are relying upon the selective cite-all method to satisfy data requirements that have not been satisfied by data submitted by UPI.

As expressly permitted under 40 CFR § 152.84 and various Federal Register notices, UPI will submit compensation offers to companies listed on EPA's Data Submitters List as of this date after you have determined that the application is acceptable and ready for approval. As stated by EPA in the Federal Register:

Before the Agency will approve this applicant, the applicant must certify that he has obtained the authorization of, or made appropriate offers to pay to, each person on the Data Submitters List. . . . As in the past, the applicant will be permitted to submit his

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Letter to G. LaRocca, April 8, 2002, page 2

certification and general offer to pay *at any time before registration is approved*. The Agency will not delay the review of the application pending receipt of these statements, but will not approve the application until they are received and determined to be in compliance.

49 Fed. Reg. 30884 (Aug. 1, 1984), *Final Rule: Pesticide Programs; Pesticide Registration and Classification Procedures; Application Procedures To Ensure Protection of Data Submitters' Rights*.

As such, we will submit a completed Certification with Respect to Citation of Data form to your office, and send the necessary data compensation offers to companies listed on the enclosed data matrix, once we obtain confirmation from your office that the enclosed data matrix is acceptable and that EPA has decided to approve the enclosed application.

UPI's technical grade bifenthrin is of a higher purity than that of the substantially similar EPA Reg. No. 279-3055. However, the enclosed studies identify that the acute oral and dermal toxicity are comparable to that of the registered product. Since it is known and well-documented for pyrethroids that the isomer ratio is of greater importance than slight differences in purity and since UPI's product has a comparable isomeric ratio to that of the registered product and does not contain impurities of toxicological concern, the UPI product should be considered as comparable to the already registered product.

With respect to physical/chemical characteristics, the data generated using the Pure Active Ingredient and already on file at the Agency is applicable regardless of the purity of the technical grade material. These data are OPPTS 830.7050 (UV/Visible Absorption), OPPTS 830.7220 (Melting Point), OPPTS 830.7950 (Vapor pressure), OPPTS 830.7370 (Dissociation Constant), OPPTS 830.7550 (Octanol/water partition coefficient). Other characteristics, such as solubility, are not appreciably affected by the minor differences in the purity of the technical material, which is insoluble in water. Inasmuch as the material is solid, OPPTS 830.7220 (boiling point) is not applicable.

Based on both 40 CFR 158.190(a) and OPPTS 830.1000, we believe that the following data requirements are not pertinent for the registration of Bifenthrin Technical Insecticide/Miticicide:

1. one year storage stability study (OPPTS 830.6317)
2. corrosion characteristics (OPPTS 830.6320)
3. oxidation/reduction (OPPTS 830.6314)
4. viscosity (OPPTS 830.7100)
5. flammability (OPPTS 830.6315)
6. explosability (OPPTS 830.6316)
7. miscibility (OPPTS 830.6319)
8. dielectric breakdown voltage (OPPTS 830.6321)

ChemReg

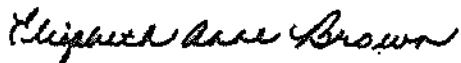
INTERNATIONAL, LLC

Letter to G. LaRocca, April 8, 2002, page 3

UPI is requesting a waiver from the requirements to assess the stability to metal and metal ions under OPPTS 830.6313, as the product is packaged, stored, and shipped in high density polyethylene and is not in contact with metals or metal ions. The submitted study meets the requirements for stability to normal and elevated temperatures under OPPTS 830.6313.

We trust that, with the enclosed documents, the Agency can expeditiously issue UPI's registration. Should you have any questions regarding the enclosed material, please do not hesitate to call.

Sincerely,



Elizabeth Anne Brown, Ph.D.

cc: UPI



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 25 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

United Phosphorus, Inc.
c/o Ms. Elizabeth A. Brown, Ph.D.
ChemReg International, LLC
1990 Old Bridge Road, Suite 201
Lake Ridge, VA 22192-2383

Dear Ms. Brown:

SUBJECT: Application for Registration
Bifenthrin Technical Insecticide/Miticide
EPA File Symbol: 70506-RI
Your Submission Dated April 11, 2002

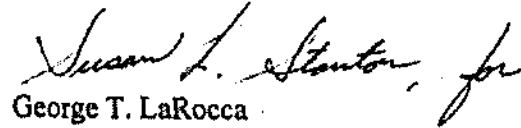
The application referred to above has been determined pursuant to 40 CFR §152.104, not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling, data and/or other information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days, you must notify the Agency within those 75 days of the date you expect to complete the application. If, after 75 days you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new application.

1. An application is considered incomplete if any pertinent item specified in §152.50 has not been submitted. Pursuant to §152.50(f) an applicant must submit materials to demonstrate that he has complied with FIFRA sec. 3(e)(1)(D) and **subpart E** of part 152 (Procedures to Ensure Protection of Data Submitters' Rights). Therefore, you must submit a completed Certification with Respect to Citation of Data (EPA Form 8570-34) indicating the Method of Data Support you are using. You must also submit a list of companies sent offers of compensation for data you are citing in support of this application.

-2-

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Susan L. Stanton, for".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

APR 19 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

UNITED PHOSPHOROUS, INC.
1209 ORANGE STREET
WILMINGTON, DE 19801

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/11/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

4/15/2002

UNITED PHOSPHORUS, INC.
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: BIFENTHRIN TECHNICAL INSECTICIDE/MITICIDE
COMPANY NAME: UNITED PHOSPHORUS, INC.
OPP IDENTIFICATION NUMBER: 294229
EPA FILE SYMBOL: 70506-RI
EPA RECEIPT DATE: 4/11/02

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact the Insecticide Branch at 703-305-7448.

Sincerely,

A handwritten signature in cursive script, reading "Patricia A. Moske".

Front End Processing Staff
Information Services Branch
Information Resources & Services Division

TRANSMITTAL DOCUMENT

Submitter

United Phosphorus, Inc

United Phosphorus, Inc.
740 Springdale Drive
Suite 204
Exton, PA 19341

ChemReg International, LLC*
2239-H Tacketts Mill Drive
Lake Ridge, VA 22192-3026

*ChemReg International is the authorized representative for United Phosphorus, Inc.

Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")
(Bifenthrin Technical Insecticide/Miticide 70506-x)

Transmittal Date

April 11, 2002

Submitted Studies

	MRID	
----		Administrative Materials
Document 1:	45654401	Brown, E.A. March 19, 2002. Bifenthrin Technical Insecticide. Product Identity, Composition, and Analysis (Group A). Compilation Report No. UPI-Bifentech-A. 219 pgs. <i>Contains Confidential Business Information.</i>
Document 2:	45654402	Joshi, C. Nov 12, 2001. Appearance (colour, physical state, and odor) of bifenthrin. JRF study number 3591. 13 pg.
Document 3:	45654403	Patel, A.H. Sept 5, 2001. Accelerated storage stability of bifenthrin. JRF study number 3220. 81 pg.
Document 4:	45654404	Tiwari, V.K. Feb. 9, 2002. Acute oral toxicity study of bifenthrin technical in rats. Jai Research Foundation. JRF Study No. 3415. 33 pages.
Document 5:	45654405	Tiwari, V.K. Feb 9, 2002. Acute dermal toxicity study of bifenthrin technical in rats. Jai Research Foundation. JRF Study No. 3416. 27 pages.

Company Official

Elizabeth Anne Brown

Company Name: ChemReg International, LLC., Authorized Representative for UPI

Company Contact: Elizabeth Anne Brown

Phone Number: 703-492-7905



456544-00

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LAKE RIDGE, VIRGINIA 22192-2383

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MAIN: 703-492-0445
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WEB SITES: www.chemreg.com
www.pesticide.net

ELIZABETH A. BROWN, PH.D.

April 8, 2002

Document Processing Desk (APPL)
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

70506-RI

Attn: George LaRocca (PM 13)

Re: Application for Registration of "Me-Too" Bifenthrin Technical Insecticide/Miticide

On behalf of our client, United Phosphorus, Inc. (UPI), we are submitting an application for a "me-too" registration of Bifenthrin Technical Insecticide/Miticide (EPA Product Code 128825). This product is substantially similar to the already registered EPA Reg No. 279-3055.

Enclosed please find:

Transmittal bibliography

Three (3) copies of each submitted study

Application form 8570-1

Five (5) copies of the proposed label

Data matrix forms for EPA and public use (Form 8570-35)

Please note that we are relying upon the selective cite-all method to satisfy data requirements that have not been satisfied by data submitted by UPI.

As expressly permitted under 40 CFR § 152.84 and various Federal Register notices, UPI will submit compensation offers to companies listed on EPA's Data Submitters List as of this date after you have determined that the application is acceptable and ready for approval. As stated by EPA in the Federal Register:

Before the Agency will approve this applicant, the applicant must certify that he has obtained the authorization of, or made appropriate offers to pay to, each person on the Data Submitters List. . . . As in the past, the applicant will be permitted to submit his

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244

Letter to G. LaRocca, April 8, 2002, page 2

certification and general offer to pay *at any time before registration is approved*. The Agency will not delay the review of the application pending receipt of these statements, but will not approve the application until they are received and determined to be in compliance.

49 Fed. Reg. 30884 (Aug. 1, 1984), *Final Rule: Pesticide Programs; Pesticide Registration and Classification Procedures; Application Procedures To Ensure Protection of Data Submitters' Rights*.

As such, we will submit a completed Certification with Respect to Citation of Data form to your office, and send the necessary data compensation offers to companies listed on the enclosed data matrix, once we obtain confirmation from your office that the enclosed data matrix is acceptable and that EPA has decided to approve the enclosed application.

UPI's technical grade bifenthrin is of a higher purity than that of the substantially similar EPA Reg. No. 279-3055. However, the enclosed studies identify that the acute oral and dermal toxicity are comparable to that of the registered product. Since it is known and well-documented for pyrethroids that the isomer ratio is of greater importance than slight differences in purity and since UPI's product has a comparable isomeric ratio to that of the registered product and does not contain impurities of toxicological concern, the UPI product should be considered as comparable to the already registered product.

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7. miscibility (OPPTS 830.6319)
8. dielectric breakdown voltage (OPPTS 830.6321)

ChemReg

INTERNATIONAL, LLC

Letter to G. LaRocca, April 8, 2002, page 3

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We trust that, with the enclosed documents, the Agency can expeditiously issue UPI's registration. Should you have any questions regarding the enclosed material, please do not hesitate to call.

Sincerely,



Elizabeth Anne Brown, Ph.D.

cc: UPI

N/ET

ChemReg

INTERNATIONAL, LLC

B

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LAKE RIDGE, VIRGINIA 22192-2383

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MAIN: 703-492-0445
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ELIZABETH A. BROWN, PH.D.

April 8, 2002

Document Processing Desk (APPL)
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
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Letter to G. LaRocca, April 8, 2002, page 2

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As such, we will submit a completed Certification with Respect to Citation of Data form to your office, and send the necessary data compensation offers to companies listed on the enclosed data matrix, once we obtain confirmation from your office that the enclosed data matrix is acceptable and that EPA has decided to approve the enclosed application.

UPI's technical grade bifenthrin is of a higher purity than that of the substantially similar EPA Reg. No. 279-3055. However, the enclosed studies identify that the acute oral and dermal toxicity are comparable to that of the registered product. Since it is known and well-documented for pyrethroids that the isomer ratio is of greater importance than slight differences in purity and since UPI's product has a comparable isomeric ratio to that of the registered product and does not contain impurities of toxicological concern, the UPI product should be considered as comparable to the already registered product.

With respect to physical/chemical characteristics, the data generated using the Pure Active Ingredient and already on file at the Agency is applicable regardless of the purity of the technical grade material. These data are OPPTS 830.7050 (UV/Visible Absorption), OPPTS 830.7220 (Melting Point), OPPTS 830.7950 (Vapor pressure), OPPTS 830.7370 (Dissociation Constant), OPPTS 830.7550 (Octanol/water partition coefficient). Other characteristics, such as solubility, are not appreciably affected by the minor differences in the purity of the technical material, which is insoluble in water. Inasmuch as the material is solid, OPPTS 830.7220 (boiling point) is not applicable.

Based on both 40 CFR 158.190(a) and OPPTS 830.1000, we believe that the following data requirements are not pertinent for the registration of Bifenthrin Technical Insecticide/Miticide:

1. one year storage stability study (OPPTS 830.6317)
2. corrosion characteristics (OPPTS 830.6320)
3. oxidation/reduction (OPPTS 830.6314)
4. viscosity (OPPTS 830.7100)
5. flammability (OPPTS 830.6315)
6. explosibility (OPPTS 830.6316)
7. miscibility (OPPTS 830.6319)
8. dielectric breakdown voltage (OPPTS 830.6321)

ChemReg

INTERNATIONAL, LLC

Letter to G. LaRocca, April 8, 2002, page 3

UPI is requesting a waiver from the requirements to assess the stability to metal and metal ions under OPPTS 830.6313, as the product is packaged, stored, and shipped in high density polyethylene and is not in contact with metals or metal ions. The submitted study meets the requirements for stability to normal and elevated temperatures under OPPTS 830.6313.

We trust that, with the enclosed documents, the Agency can expeditiously issue UPI's registration. Should you have any questions regarding the enclosed material, please do not hesitate to call.

Sincerely,



Elizabeth Anne Brown, Ph.D.

cc: UPI

TRANSMITTAL DOCUMENT

Submitter

United Phosphorus, Inc

United Phosphorus, Inc.
740 Springdale Drive
Suite 204
Exton, PA 19341

ChemReg International, LLC*
2239-H Tacketts Mill Drive
Lake Ridge, VA 22192-3026

*ChemReg International is the authorized representative for United Phosphorus, Inc.

Regulatory action in support of which this package is submitted

New Product Registration ("Me-Too")
(Bifenthrin Technical Insecticide/Miticide 70506-x)

Transmittal Date

April 11, 2002

Submitted Studies

	MRID	
----		Administrative Materials
Document 1:		Brown, E.A. March 19, 2002. Bifenthrin Technical Insecticide. Product Identity, Composition, and Analysis (Group A). Compilation Report No. UPI-Bifentech-A. 219 pgs. <i>Contains Confidential Business Information.</i>
Document 2:		Joshi, C. Nov 12, 2001. Appearance (colour, physical state, and odor) of bifenthrin. JRF study number 3591. 13 pg.
Document 3:		Patel, A.H. Sept 5, 2001. Accelerated storage stability of bifenthrin. JRF study number 3220. 81 pg.
Document 4:		Tiwari, V.K. Feb. 9, 2002. Acute oral toxicity study of bifenthrin technical in rats. Jai Research Foundation. JRF Study No. 3415. 33 pages.
Document 5:		Tiwari, V.K. Feb 9, 2002. Acute dermal toxicity study of bifenthrin technical in rats. Jai Research Foundation. JRF Study No. 3416. 27 puges.

Company Official

Elizabeth Anne Brown

Company Name: ChemReg International, LLC., Authorized Representative for UPI

Company Contact: Elizabeth Anne Brown


Phone Number: 703-492-7905

NIFT

B

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

	United States	<input checked="" type="checkbox"/> Registration	OPP Identifier Number 294229
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 70508- R2	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bifenthrin Technical Insecticide/Miticide	PM # 18-03	
5. Name and Address of Applicant (Include ZIP Code) United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. 279-3055 Product Name Bifenthrin Technical Insecticide/Miticide	

Section - II

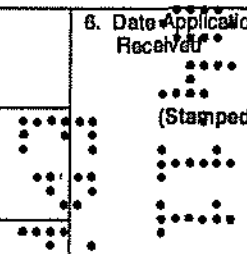
<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> Agency letter dated "Me Too" Application
<input type="checkbox"/> Notification - Explain below	<input checked="" type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Section III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) high molecular HDPE bags in HDPE drums	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 25 kg		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Elizabeth Anne Brown		Title ChemReg International, LLC Authorized representative	
		Telephone No. (Include Area Code) 703-492-7805	
Certification I certify that the statements I have made on this form and all attachments hereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			8. Date Application Received 
2. Signature <i>Elizabeth Anne Brown</i>		3. Title ChemReg International, LLC Authorized representative	
4. Typed Name Elizabeth Anne Brown		5. Date 4-11-2002	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (Original) Yellow - Applicant Copy



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
294229

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(II), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) <div style="text-align: right; font-size: 1.5em;">252</div>
2. Signature		3. Title			
4. Typed Name		5. Date			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.51 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

294229
294229

Application for Pesticide - Section I

1. Company/Product Number 12	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM# 03	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
Certification must be submitted If "Yes" Unit Packaging wgt. _____ No. per container _____		If "Yes" Package wgt _____ No. per container _____			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point. (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name		Title	
		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 254
2. Signature		3. Title	
4. Typed Name		5. Date	

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2. Confidential Statement of Formula (EPA Form 8570-4);
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4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

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2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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- 1-5. Self-explanatory.
6. EPA Use Only.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: March 20, 20002	EPA Reg No./ File Symbol 70506-	Page 1 of 3
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1 (830.1550)	Chemical identity		United Phosphorus Inc (UPI)	Own	
61-2a (830.1620)	Starting materials and manufacturing process		UPI	Own	
61-2b (830.1670)	Formation of impurities		UPI	Own	
62-1 (830.1700)	Preliminary analysis		UPI	Own	
62-2 (830.1750)	Certification of limits		UPI	Own	
62-3 (830.1800)	Analytical method		UPI	Own	
63-2 (830.6302)	Color		UPI	Own	
63-3 (830.6303)	Physical state		UPI	Own	
63-4 (830.6304)	Odor		UPI	Own	
None (830.7050)	UV/Visible Absorption	CITE ALL	FMC Corp Agricultural Products Group (FMC); The Scotts Co (Scotts); The Andersons Lawn Fertilizer Division, Inc. (Andersons)	pay	
63-5 (830.7220)	Melting point	CITE ALL	FMC, Scotts, Andersons	Pay	
63-7 (830.7300)	Density	CITE ALL	FMC, Scotts, Andersons		
63-8 (830.7840)	Solubility	CITE ALL	FMC, Scotts, Andersons	pay	
63-9 (830.7950)	Vapor pressure	CITE ALL	FMC, Scotts, Andersons	Pay	
63-10 (830.7370)	Dissociation constant	CITE ALL	FMC, Scotts, Andersons	Pay	
63-11 (830.7550)	Octanol/water partition	CITE ALL	FMC, Scotts, Andersons	Pay	
63-12 (830.7000)	pH		UPI	own	
63-13 (830.6313)	Stability		UPI	own	
71-1b (850.2100)	Avian acute oral toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
71-2 (850.2200)	Avian dietary toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 4/11/2002
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 20, 20002

Applicant's/Registrant's Name and Address:
United Phosphorus, Inc.
423 Riverview Plaza
Trenton, NJ 08611

Ingredient: Bifenthrin (PC 128825)

*Note: Recently
Submitted inhalation
and derm sens
studies for FMC's
tech are under
review. Per George -
Don't need to cite these.*

EPA Reg No./ File Symbol
70506-

Page 2 of 3

Product: Bifenthrin Technical Insecticide/Miticide

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
71-4 (850.2300)	Avian reproduction	CITE ALL	FMC, Scotts, Andersons	Pay	
72-1 (850.1075)	Fish acute toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-2 (850.1010)	Invertebrate toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-3 (850.1025 - 1055)	Estuarine/marine toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1300)	Invertebrate Chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-4 (850.1350)	Invertebrate chronic toxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
72-5 (850.1400)	Fish life early life cycle	CITE ALL	FMC, Scotts, Andersons	Pay	
141-1 (850.3020)	Honeybee acute contact toxicity	CITE ALL	FMC, Scotts, Andersons	pay	
81-1 (870.1100)	Acute oral- rat		UPI	Own	
81-2 (870.1200)	Acute dermal- rabbit/rat		UPI	Own	
81-3 (870.1300)	Acute inhalation - rat	00155286	FMC	Old	
81-4 (870.2400)	Primary eye irritation - rabbit	00132522 ✓	FMC	Old	
81-5 (870.2500)	Primary dermal irritation - rabbit	00132521 ✓	FMC	Old	
81-6 (870.2600)	Dermal sensitization	00132523 ✓	FMC	Old	
81-8 (870.6200)	Acute neurotoxicity	CITE ALL	FMC, Scotts, Andersons	Pay	
82-1 (870.3100)	90-Day feeding	CITE ALL	FMC, Scotts, Andersons	pay	
82-2 (870.3200)	21-Day dermal toxicity - rats	CITE ALL	FMC, Scotts, Andersons	Pay	
82-7 (none)	Subchronic neurotoxicity - rat	CITE ALL	FMC, Scotts, Andersons	pay	
83-1a (870.4100)	Chronic feeding toxicity - rodent	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-1b (870.4100)	Chronic feeding toxicity - dog	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2a (870.4200)	Oncogenicity - rat	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-2b (870.4200)	Oncogenicity - mouse	CITE-ALL	FMC, Scotts, Andersons	Pay	
83-3a (870.3700)	Teratogenicity - rat	CITE-ALL	FMC, Scotts, Andersons	Pay	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

4/11/2002



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 20, 20002	EPA Reg No./ File Symbol 70506-	Page 3 of 3
Applicant's/Registrant's Name and Address: United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611	Product: Bifenthrin Technical Insecticide/Miticide	
Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3b (870.3700)	Teratogenicity - rabbit	CITE-ALL	FMC, Scotts, Andersons	Pay	
84-2	Mutagenicity studies	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-1 (870.7485)	General metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
85-2	Dermal absorption	CITE-ALL	FMC, Scotts, Andersons	Pay	
161-1	Hydrolysis	CITE ALL	FMC, Scotts, Andersons	Pay	
161-2	Photodegradation in water	CITE ALL	FMC, Scotts, Andersons	Pay	
162-1	Aerobic soil metabolism	CITE-ALL	FMC, Scotts, Andersons	Pay	
163-1	Adsorption/desorption	CITE ALL	MC, Scotts, Andersons	Pay	
164-1 (875.2200)	Field soil dissipation	CITE-ALL	FMC, Scotts, Andersons	Pay	
165-4	Bioaccumulation in fish	CITE-ALL	FMC, Scotts, Andersons	pay	
Special studies	Other	CITE ALL	Pyrethroid Working Group	pay	
132-1 (857.2100)	Foliar residue dissipation	CITE ALL	FMC, Scotts, Andersons	Pay	
133-3 (875.2400, 2500)	Dermal exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
133-4 (857.2500)	Inhalation exposure	CITE ALL	UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
201-1, 202-1 (840.1100, 835.4200)	Spray drift and droplet size	CITE ALL	UPI is a member of the Spray Drift Task Force	Own	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

4/11/2002



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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			MC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			Pyrethroid Working Group	pay	
			FMC, Scotts, Andersons	Pay	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Spray Drift Task Force	Own	

Signature

Elizabeth Anne Brown

Name and Title

Elizabeth Anne Brown, ChemReg International, LLC
Registration Agent

Date

4/11/2002



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Ingredient: Bifenthrin (PC 128825)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
200			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			UPI	Own	
			UPI	Own	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC	Old	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 4/11/2002
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			MC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	Pay	
			FMC, Scotts, Andersons	pay	
			Pyrethroid Working Group	pay	
			FMC, Scotts, Andersons	Pay	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Ag Re-entry task force; UPI is a member of the Outdoor Residential Task Force	Own	
			UPI is a member of the Spray Drift Task Force	Own	

201140

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown, ChemReg International, LLC Registration Agent	Date 4/11/2002
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United Phosphorus, Inc.

423 Riverview Plaza
Trenton, NJ 08611
(609) 392-8200 x 18 (phone)
(609) 392-0808 (fax)

Rebecca A. Clemmer
Regulatory Affairs Manager

November 2, 2004

Mr. George LaRocca (PM 13)
Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protections Agency
1801 Bell Street
Arlington, VA 22202

Re: Bifenthrin Technical Insecticide, EPA Reg. No. 70506-18
Submission of Production Information

Dear Mr. LaRocca:

In its Notice of Pesticide Registration, USEPA required United Phosphorus to submit production information for this product for the 2004 fiscal year. This product is manufactured by United Phosphorus in India, and we hereby report that between the dates of Sept. 30, 2003 and October 1, 2004, we have imported [REDACTED] of Bifenthrin Technical.

No data are being submitted with this application and no fees are applicable under the requirements of PRIA.

Please contact me if you have any questions.

Very truly yours,

A handwritten signature in cursive script that reads 'Rebecca A. Clemmer'.

Rebecca A. Clemmer
rclemmer@upi-usa.com

